

External Cephalic Version: No Drop in C-Sections

BY KATE JOHNSON

FROM THE ANNUAL MEETING OF
THE SOCIETY OF OBSTETRICIANS AND
GYNAECOLOGISTS OF CANADA

MONTREAL – Early external cephalic version increases the likelihood of cephalic presentation at birth, but does not result in fewer cesarean sections compared with later cephalic version, based on the results of an internation-

al, multicenter, randomized controlled trial.

In addition, there was a trend toward greater risk of preterm birth when the procedure was done early, defined as between the 34th and 35th weeks, reported Dr. George Carson, one of the investigators on the Early External Cephalic Version 2 (ECV2) Trial.

“This is actually very disappointing,” he said in an interview at the meeting.

“It is worth trying to investigate why turning the baby didn’t result in a reduction in cesarean sections. Obviously the purpose of this was not to turn the baby – it was to reduce cesarean sections – and that didn’t happen, and that’s disappointing.”

The study randomized 1,532 women with breech presentations to either an early version or a later version performed at 37 weeks. The primary end

point was the rate of cesarean section, with a secondary end point of preterm birth.

“The concern was that in performing version one might precipitate preterm birth, and so this could be the adverse effect of the attempt to turn the baby,” noted Dr. Carson, director of maternal-fetal medicine at Regina (Sask.) General Hospital.

Baseline characteristics including par-

ParaGard[®] T 380A[®] intrauterine copper contraceptive

Brief Summary

(See package brochure for full prescribing information)

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

ParaGard[®] T 380A Intrauterine Copper Contraceptive should be placed and removed only by healthcare professionals who are experienced with these procedures.

INDICATIONS AND USAGE

ParaGard[®] is indicated for intrauterine contraception for up to 10 years. The pregnancy rate in clinical studies has been less than 1 pregnancy per 100 women each year.

CONTRAINDICATIONS

ParaGard[®] should not be placed when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy
2. Abnormalities of the uterus resulting in distortion of the uterine cavity
3. Acute pelvic inflammatory disease, or current behavior suggesting a high risk for pelvic inflammatory disease
4. Postpartum endometritis or postabortal endometritis in the past 3 months
5. Known or suspected uterine or cervical malignancy
6. Genital bleeding of unknown etiology
7. Mucopurulent cervicitis
8. Wilson's disease
9. Allergy to any component of ParaGard[®]
10. A previously placed IUD that has not been removed

WARNINGS

1. Intrauterine Pregnancy

If intrauterine pregnancy occurs with ParaGard[®] in place and the string is visible, ParaGard[®] should be removed because of the risk of spontaneous abortion, premature delivery, sepsis, septic shock, and, rarely, death. Removal may be followed by pregnancy loss.

If the string is not visible, and the woman decides to continue her pregnancy, check if the ParaGard[®] is in her uterus (for example, by ultrasound). If ParaGard[®] is in her uterus, warn her that there is an increased risk of spontaneous abortion and sepsis, septic shock, and, rarely, death. In addition, the risk of premature labor and delivery is increased.

Human data about risk of birth defects from copper exposure are limited. However, studies have not detected a pattern of abnormalities, and published reports do not suggest a risk that is higher than the baseline risk for birth defects.

2. Ectopic Pregnancy

Women who become pregnant while using ParaGard[®] should be evaluated for ectopic pregnancy. A pregnancy that occurs with ParaGard[®] in place is more likely to be ectopic than a pregnancy in the general population. However, because ParaGard[®] prevents most pregnancies, women who use ParaGard[®] have a lower risk of an ectopic pregnancy than sexually active women who do not use any contraception.

3. Pelvic Infection

Although pelvic inflammatory disease (PID) in women using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs within 20 days following insertion. Therefore, the visit following the first post-insertion menstrual period is an opportunity to assess the patient for infection, as well as to check that the IUD is in place. Since pelvic infection is most frequently associated with sexually transmitted organisms, IUDs are not recommended for women at high risk for sexual infection. Prophylactic antibiotics at the time of insertion do not appear to lower the incidence of PID.

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and, rarely, death. It is therefore important to promptly assess and treat any woman who develops signs or symptoms of PID.

Guidelines for treatment of PID are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia at www.cdc.gov or 1-800-311-3435. Antibiotics are the mainstay of therapy. Most healthcare professionals also remove the IUD.

The significance of actinomyces-like organisms on Papanicolaou smear in an asymptomatic IUD-user is unknown, and so this finding alone does not always require IUD removal and treatment. However, because pelvic actinomycosis is a serious infection, a woman who has symptoms of pelvic infection possibly due to actinomyces should be treated and have her IUD removed.

4. Immunocompromise

Women with AIDS should not have IUDs inserted unless they are clinically stable on antiretroviral therapy. Limited data suggest that asymptomatic women infected with human immunodeficiency virus may use intrauterine devices. Little is known about the use of IUDs in women who have illnesses causing serious immunocompromise. Therefore these women should be carefully monitored for infection if they choose to use an IUD. The risk of pregnancy should be weighed against the theoretical risk of infection.

5. Embedment

Partial penetration or embedment of ParaGard[®] in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

6. Perforation

Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove ParaGard[®] promptly, since the copper can lead to intraperitoneal adhesions. Intestinal penetration, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

7. Expulsion

Expulsion can occur, usually during the menses and usually in the first few months after insertion. There is an increased risk of expulsion in the nulliparous patient. If unnoticed, an unintended pregnancy could occur.

8. Wilson's Disease

Theoretically, ParaGard[®] can exacerbate Wilson's disease, a rare genetic disease affecting copper excretion.

PRECAUTIONS

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

1. Information for patients

Before inserting ParaGard[®] discuss the Patient Package Insert with the patient, and give her time to read the information. Discuss any questions she may have concerning ParaGard[®] as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

2. Insertion precautions, continuing care, and removal. (See Package Brochure for INSTRUCTIONS FOR USE.)

3. Vaginal bleeding

In the 2 largest clinical trials with ParaGard[®] (see ADVERSE REACTIONS, Table 2), menstrual changes were the most common medical reason for discontinuation of ParaGard[®]. Discontinuation rates for pain and bleeding combined are highest in the first year of use and diminish thereafter. The percentage of women who discontinued ParaGard[®] because of bleeding problems or pain during these studies ranged from 11.9% in the first year to 2.2% in year 9. Women complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue ParaGard[®]. (See ADVERSE REACTIONS.)

4. Vasovagal reactions, including fainting

Some women have vasovagal reactions immediately after insertion. Hence, patients should remain supine until feeling well and should be cautious when getting up.

5. Expulsion following placement after a birth or abortion

ParaGard[®] has been placed immediately after delivery, although risk of expulsion may be higher than when ParaGard[®] is placed at times unrelated to delivery. However, unless done immediately postpartum, insertion should be delayed to the second postpartum month because insertion during the first postpartum month (except for immediately after delivery) has been associated with increased risk of perforation.

ParaGard[®] can be placed immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Placement after second trimester abortion is associated with a higher risk of expulsion than placement after the first trimester abortion.

6. Magnetic resonance imaging (MRI)

Limited data suggest that MRI at the level of 1.5 Tesla is acceptable in women using ParaGard[®]. One study examined the effect of MRI on the CU-7[®] Intrauterine Copper Contraceptive and Lippes Loop[™] Intrauterine devices. Neither device moved under the influence of the magnetic field or heated during the spin-echo sequences usually employed for pelvic imaging. An in vitro study did not detect movement or temperature change when ParaGard[®] was subjected to MRI.

7. Medical diathermy

Theoretically, medical (non-surgical) diathermy (short-wave and microwave heat therapy) in a patient with a metal-containing IUD may cause heat injury to the surrounding tissue. However, a small study of eight women did not detect a significant elevation of intrauterine temperature when diathermy was performed in the presence of a copper IUD.

8. Pregnancy

ParaGard[®] is contraindicated during pregnancy. (See CONTRAINDICATIONS and WARNINGS.)

9. Nursing mothers

Nursing mothers may use ParaGard[®]. No difference has been detected in concentration of copper in human milk before and after insertion of copper IUDs. The literature is conflicting, but limited data suggest that there may be an increased risk of perforation and expulsion if a woman is lactating.

10. Pediatric use

ParaGard[®] is not indicated before menarche. Safety and efficacy have been established in women over 16 years old.

ADVERSE REACTIONS

The most serious adverse events associated with intrauterine contraception are discussed in WARNINGS and PRECAUTIONS. These include:

Intrauterine pregnancy	Pelvic infection
Septic abortion	Perforation
Ectopic pregnancy	Embedment

Table 2 shows discontinuation rates from two clinical studies by adverse event and year.

Table 2. Summary of Rates (No. per 100 Subjects) by Year for Adverse Events Causing Discontinuation

Adverse Event	Year									
	1	2	3	4	5	6	7	8	9	10
Pregnancy	0.7	0.3	0.6	0.2	0.3	0.2	0.0	0.4	0.0	0.0
Expulsion	5.7	2.5	1.6	1.2	0.3	0.0	0.6	1.7	0.2	0.4
Bleeding/Pain	11.9	9.8	7.0	3.5	3.7	2.7	3.0	2.5	2.2	3.7
Other Medical Event	2.5	2.1	1.6	1.7	0.1	0.3	1.0	0.4	0.7	0.3
No. of Women at Start of Year	4932	3149	2018	1121	872	621	563	483	423	325

*Rates were calculated by weighting the annual rates by the number of subjects starting each year for each of the Population Council (3,536 subjects) and the World Health Organization (1,396 subjects) trials.

The following adverse events have also been observed. These are listed alphabetically and not by order of frequency or severity.

Anemia	Menstrual flow, prolonged
Backache	Menstrual spotting
Dysmenorrhea	Pain and cramping
Dyspareunia	Urticarial allergic skin reaction
Expulsion, complete or partial	Vaginitis
Leukorrhea	

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400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677

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VITALS **Major Finding:** Women randomized to early or late external cephalic version had nonsignificant differences in cesarean section rate (52% vs. 56%), with a trend toward more preterm deliveries in the early-version group.

Data Source: A study that randomized 1,532 women with breech presentations to either an early external cephalic version or a later version performed at 37 weeks.

Disclosures: Dr. Carson said he had no relevant disclosures. The trial was funded by the Canadian Institutes of Health Research.

ity, types of breech presentation, and anterior placenta were similar in both groups.

Cephalic presentation at the time of delivery, due to either successful external version or spontaneous version, was higher in the early-version group (59% vs. 51%), and the difference reached statistical significance, said Dr. Carson. However, there was not a statistically significant difference in the cesarean section rate: 52% in the early group and 56% in the late group.

“More women delivered vaginally than was anticipated in the delayed group – due to spontaneous conversion and a small number of women who decided to deliver vaginally even though their baby was still breech,” he said, adding that overall, the cesarean section rate was high.

“Very few of these were done for non-reassuring monitoring. They were done in places that do a lot of sections anyway, so being cephalic was not in any way a guarantee that one wouldn’t have a section done,” he said.

The increased rate of preterm delivery in the early-version group (6.5% vs. 4.4% in the late group) was not statistically significant, but it strengthens the argument against attempting an early cephalic version, said Dr. Carson.

“What I tell the women that I am trying to do a version on is, if we don’t do it ... they’ve got about a 70% chance of a cesarean section. If we do it, that could be reduced to about 50%. But my chance of getting the fetus around is only about 50%.

“And if we push hard on the uterus, maybe we could make them deliver prematurely. It won’t be very premature, but it’s still better to be term than 35 weeks,” he said. ■