
Compliance with pregnancy prevention measures during isotretinoin therapy

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Background: Approximately 150 women annually become pregnant while taking isotretinoin despite participation in the iPLEDGE program. Noncompliance with the requirement to be abstinent or use 2 contraceptive methods may be a contributing factor.

Objective: We sought to determine the degree of adherence to contraception or abstinence among women taking isotretinoin.

Methods: We conducted an anonymous survey of women of childbearing potential taking isotretinoin for at least 2 months.

Results: Among 75 participants, 21 (28%) chose abstinence as their primary means of pregnancy prevention, of whom 4 (19%) were sexually active during treatment. The most commonly chosen contraceptive methods among the 39 women who were sexually active were condoms (35, 90%) and oral contraceptive pills (18, 46%). Twelve women (31%) admitted to having intercourse at least once using 1 or fewer forms of contraception; 10 failed to use condoms, and 1 reported completely unprotected intercourse. Among sexually active oral contraceptive pill users, 7 (39%) reported missing 1 or more pills in the previous month.

Limitations: Data were self-reported, thus participants may have inaccurately reported contraception use.

Conclusions: Encouraging the use of highly effective, patient-independent contraception and limiting abstinence to women who have never been sexually active may further reduce the rate of isotretinoin-exposed pregnancies. (J Am Acad Dermatol 2014;70:55-9.)

Key words: acne; condoms; contraception; intrauterine device; iPLEDGE; isotretinoin; oral contraceptive pills.

Although isotretinoin has revolutionized the treatment of severe acne vulgaris, women of childbearing potential must avoid pregnancy during treatment. To facilitate this, the iPLEDGE program was established and requires monthly pregnancy tests, identification of contraceptive

methods, and qualifying questions for patients.¹ However, the isotretinoin-exposed pregnancy rate is not significantly lower than it was before iPLEDGE initiation,² and approximately 150 isotretinoin-exposed pregnancies occurred annually from 2008 through 2011.³ The iPLEDGE program relies on the

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Ms Collins and Ms Moreau contributed equally to this work.

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female patient to consistently use contraception or be abstinent. However, inconsistent use of oral contraceptive pills (OCPs) and condoms is common.^{4,5} To better understand the factors that put women at risk for pregnancy during isotretinoin therapy, we conducted an anonymous survey of women of childbearing potential taking isotretinoin to assess their choice of abstinence or contraceptive methods and compliance with their chosen contraceptive methods while taking isotretinoin.

METHODS

Survey and subjects

This study was determined to be exempt from full board review by the University of Pittsburgh (PRO11040032, April 27, 2011) and Loyola University of Chicago (204602, July 17, 2012) institutional review boards. We invited women 18 years and older of childbearing potential (per iPLEDGE guidelines)⁶ taking isotretinoin for at least 2 months to take an anonymous 29-question survey containing items regarding contraceptive choices during isotretinoin therapy; compliance with abstinence or contraception during therapy; reasons for noncompliance, when applicable; and demographic information. The survey was reviewed for face validity by an expert in survey-based research, a dermatologist (L. K. F.) and a women's health specialist (E. B. S.). Questions regarding contraceptive use were used in a previous study.⁷ We piloted the initial survey with 4 women and generated a refined, final survey based on feedback.

Subjects were given the survey when they arrived for their dermatology visit and completed it in a private room without their health care provider present. Completed surveys were placed in a locked box by the subject to ensure confidentiality. The anonymous nature of the survey was explained to subjects, both verbally and in a letter attached to the front of each survey. Subjects were assured that responses would not impact their current or future care.

Statistical analysis

We calculated the proportion of participants with specific demographic traits. We used χ^2 tests to compare traits of women who chose abstinence versus 2 forms of contraception for iPLEDGE. For

women who had been sexually active since starting isotretinoin, we calculated the proportion who used each contraceptive method within 3 months of starting isotretinoin, pledged to each method, and admitted to using fewer than 2 forms of contraception since starting isotretinoin. We also calculated the proportion of women who missed 1 or more OCP(s)

in the preceding month. Finally, we collected data on the contraceptives that were most frequently missed by participating women and reasons given for contraceptive nonuse.

RESULTS

Participant demographics

Eighty women were invited to participate, and 75 (94%) completed surveys. Participant demographics are presented in [Table I](#). Twenty-one participants (28%) chose abstinence as their primary

method of pregnancy prevention. Women who chose abstinence were younger and less likely to be black than women who did not choose abstinence ($P = .03$). Seven women (33%) who chose abstinence were previously sexually active. Four women (19%) who chose abstinence admitted to having intercourse while registered in iPLEDGE, all of whom were previously sexually active.

Contraceptive choices and compliance among sexually active women taking isotretinoin

Among the 39 women who reported having vaginal sex with a man during treatment with isotretinoin, the most commonly chosen forms of contraception were male condoms ($n = 35$, 90%) and OCPs ($n = 18$, 46%) ([Table II](#)). Although 4 women who chose abstinence admitted to sexual activity during treatment, 2 of these women did use 2 forms of contraception during sexual activity; both reported using male condoms and OCPs. Among sexually active women in our study, 12 (31%) admitted to not using 2 forms of contraception at least once during therapy, and 1 (3%) reported completely unprotected intercourse ([Table III](#)). Among those who had sex using only 1 form of contraception, 10 did not use the condoms they had agreed to use for contraception, representing a noncompliance rate of 29% for condoms among those who registered to use them in iPLEDGE. Reasons selected for not using contraception included: "I don't like using that form

CAPSULE SUMMARY

- In the United States, about 150 women annually become pregnant during isotretinoin treatment.
- Our study suggests noncompliance with contraception or abstinence is common during isotretinoin treatment.
- Increased use of patient-independent contraception and limiting use of abstinence to previously sexually inactive women may decrease fetal exposure to isotretinoin.

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