Original Article

Women's Experiences Regarding Isotretinoin Risk Reduction Counseling in Riyadh

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Abstract

Context: Isotretinoin is an effective acne treatment and a known teratogen. Contraception counseling may reduce isotretinoin-exposed pregnancies. **Aims:** The aim of the study is to assess the efficacy of contraception counseling in married females of childbearing age who are on isotretinoin or have used isotretinoin in the past 6 months. **Settings and Design:** This cross-sectional study in dermatology clinics at multiple centers in Riyadh, Saudi Arabia, between June and November, 2017. **Subjects and Methods:** Cross sectional study using surveys filled out by married women of child bearing age who were taking isotretenoin during the past 6 months. The questionnaires were distributed in paper as well as electronic version. **Statistical Methods Used:** Descriptive analysis was primarily done. **Results:** Most of the patients who received isotretinoin belong to the age group of 33–40 years, married females. Doctors discussed teratogenicity risks in 81% of the patients, but only 44% of patients received written information about risks and 52% signed the consent form. Contraception methods were discussed in 58% of patients. Only 49% of patients were advised to start contraception 1 month before starting isotretinoin. About 79% did not do pregnancy tests while on isotretinoin. **Conclusions:** This study has identified a gap in risk reduction counseling in married females who are on isotretinoin. Measures such as providing written materials explaining teratogenicity risks associated with isotretinoin, referring patients to specialist for starting contraception before prescribing isotretinoin, and ensuring strict adherence to monthly pregnancy test starting 1 month before, during, and 1 month after the treatment may help minimize the teratogenicity risk.

Keywords: Acne, counseling, isotretinoin, teratogenicity

Introduction

Acne vulgaris is a common disease with significant psychological impact on patients.[1] Many females seek medical care for this issue, and often, they are of childbearing age.[2] Isotretinoin is the most effective treatment for moderate-to-severe acne vulgaris,[3] and it is the most commonly used drug in acne patients aged 13–45 years.[4] In addition to the many side effects associated with isotretinoin, most concerning is teratogenicity.[5] At least two methods of contraception are indicated for patients who might otherwise become pregnant, and pregnancy prevention counseling is required. We assess the prevalence of contraception counseling in women who were prescribed isotretinoin.

Subjects and Methods

This was a cross-sectional study using paper and electronic data sheets filled out by married females of childbearing age who were taking isotretinoin or used it during the past 6 months. It took place in the outpatient clinics at multiple centers, including private clinics and governmental hospitals, in Riyadh, Saudi Arabia. The data were collected from June 2017 through November 2017, and the sample included 102 women aged 33–40 years (mean: 36 years). All patients signed informed consent documents to enroll, and the study protocol was approved by the Research Committee at Security Forces Hospital. The prescribing physicians were kept anonymous.

Statistical analysis

Data were collected and stored and managed using Excel 2010® software. Data were analyzed using SPSS® version 21.0

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(IBM Inc., Chicago, Illinois, USA). Descriptive analysis was primarily done, where categorical variables were presented in the form of frequencies and percentages.

Results

The majority of our sample (102 women) belonged to the 33–40-year-old age group; they were married and were university graduates. About 82.4% of our patients were prescribed isotretinoin by a dermatologist, 4.9% were prescribed the medication by a family physician, and 12.7% received prescriptions from other specialists. In terms of the gender of the physicians, 45.1% were female and 54.9% were male. The prescribing physicians discussed the isotretinoin teratogenicity risks with 81.4% of the patients. Only 44.1% reported receiving written information.

More than half of the patients, i.e., 58.8% were informed about contraception methods, and 8.8% were referred to specialists to start contraception. In addition, 49% were advised to begin contraception 1 month before starting the isotretinoin. About 63.7% of the physicians did not advise the patients to use two contraception methods while taking isotretinoin. Moreover, the vast majority of the physicians (87.3%) did not advise the patients to start isotretinoin on the 2nd or 3rd day of their menstrual cycle. One-half of the physicians (50%) did not advise their patients to continue contraception for at least 1 month after taking the last dose of isotretinoin. In addition, 52% of the physicians requested pregnancy tests before starting the isotretinoin. Of the patients, 79.4% did not have monthly pregnancy tests done while taking the isotretinoin, and only 52% of patients signed the consent before starting isotretinoin.

Discussion

Isotretinoin is a Food and Drug Administration (FDA) approved medication for acne. It has several side effects, the most serious of which is teratogenicity. Therefore, in the Consensus Conference held in February 2002, the American Academy of Dermatology provided an approach for reproductive concerns and isotretinoin use to reduce the teratogenicity risk. They concluded that all women must have contraceptive counseling and must use two contraception methods. They also recommended requiring dermatologists to refer patients to a gynecologist or primary care provider for contraceptive counseling and a prescription. In addition, females of childbearing age must follow the pregnancy testing guidelines in the isotretinoin packaging, especially a second pregnancy test done at the onset of menses. Moreover, emergency contraception should be considered in women who are not using two methods of contraception but have had an intercourse. A history of the adjuvant use of medications and dietary/herbal supplements is recommended, because these may reduce the effectiveness of contraceptives. Finally, a patient should not be pregnant before starting, during, and for 1 month after stopping the use of isotretinoin.[6]

Several measures have been taken in other countries to reduce risk of teratogenicity. For instance, in the United States, there have been a series of risk management programs (RMPs) implemented to prevent pregnant females from using isotretinoin and to prevent nonpregnant females from getting pregnant during its use. The first RMP was established by Hoffman-La Roche in 1982 when they began distributing isotretinoin with a warning on the label. In 1983, red label stickers were added in the pharmacies. Later, in 1988, the second RMP was developed, and it was called the Pregnancy Prevention Program (PPP). The PPP included the following (in addition to what was required for the first RMP): An avoid pregnancy icon on the drug box, a patient consent form, a pregnancy test before starting treatment, and the selection of two forms of birth control. In 2001, Roche built on the PPP and created a third new RMP called the System to Manage Accutane Related Teratogenicity, which included three new points (in addition to what was mentioned in the PPP) as follows: two pregnancy tests before starting treatment, pharmacists must give a medication guide with the prescription, and the use of qualification stickers by registered prescribers. Finally, the last RMP, iPLEDGE, was published in 2006 due to the failure of the previous RMPs in preventing patients from becoming pregnant while on isotretinoin. It included all of the items mentioned above, except the use of qualification stickers by a registered prescriber. In addition, it required the database registration of patients, prescribers, pharmacists, and wholesalers, as well as monthly pregnancy tests, patient qualifying questions, and the monthly identification of contraceptive methods by both the patients and doctors.[7]

The purpose of our study was to assess the prevalence of contraception counseling on married females of childbearing age. We found that physicians need to improve their risk reduction counseling skills regarding married females taking isotretinoin. Most of the participating physicians were male dermatologists, whether this would represent a cultural barrier to discuss contraception methods is not clear. While the majority of the doctors discussed the teratogenicity risk with their patients, most of the patients did not receive any written information about those risks. Moreover, the dermatologists were almost the sole source of contraception counseling. They did not refer the patients to specialists for contraception. In addition, they frequently did not advise their patients to begin contraception 1 month before starting the isotretinoin, use two contraception methods while on isotretinoin, start isotretinoin on the 2nd or 3rd day after their menstrual cycle, and continue contraception 1 month after the last dose of isotretinoin. Each of these is designed to help reduce the risk of an unintended pregnancy. A larger number of isotretinoin-affected pregnancies occur in women utilizing condoms and oral contraceptives. However, intrauterine contraceptives and subdermal implants are over 20 times more successful than oral contraceptives,[3] thus stressing the importance of proper contraceptive counseling.

Finally, while some of the physicians requested pregnancy tests before starting the isotretinoin, the majority did not request monthly pregnancy tests while their patients were taking the isotretinoin.

When comparing our study with the previously mentioned guidelines and RMPs, it seems that they were all successful in increasing the patients' awareness of the risk of teratogenicity, but there was a clear deficit in the contraception counseling. Therefore, we recommend that the dermatologists' commitment to the guidelines should be emphasized. In addition, several measures, such as providing written materials describing the isotretinoin teratogenicity risks, referring patients to specialists for contraception before prescribing isotretinoin, and ensuring strict adherence to the monthly pregnancy tests starting 1 month before, during, and 1 month after treatment, will help to minimize the teratogenicity risk.

Conclusions

This study has identified a gap in risk reduction counseling in married females who are on isotretinoin. Measures such as providing written materials explaining teratogenicity risks associated with isotretinoin, referring patients to specialist for starting contraception before prescribing isotretinoin, and ensuring strict adherence to monthly pregnancy test starting 1 month before, during, and 1 month after the treatment may help minimize the teratogenicity risk.

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Conflicts of interest

There are no conflicts of interest.

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