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RESEARCH ARTICLE

A Survey on the most common side effects of Isotretinoin among A Group of Syrian Patients

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ABSTRACT:

Acne vulgaris is considered one of the most important cutaneous conditions affecting people in the society at the ages of adolescence and youth. There are many topical treatments along with systemic treatments that can be used to treat it. Isotretinoin is one of the most popular medications that can be used to treat acne vulgaris. Its use can be accompanied by serious side effects; especially teratogenicity. We aimed of this study to evaluate the most common side effects associated to oral isotretinoin intake among the Syrian society to increase the awareness among young adults. We designed an electronic questionnaire containing 20 questions and directed to patients who are treated with oral isotretinoin; taking in consideration the privacy of the questionnaire. 320 individuals (292 females – 28 males from all Syrian communities answered the questionnaire. Among all participants, 8.4% had taken oral isotretinoin without a medical prescription and 55% (176 of 320) had not done liver function tests before starting the course. We noticed that the most frequent side effect was chapped and dry lips 96.3%, and secondly dermatoxerasia 81.6%. It was surprising that 55.6% of all participants suffered from mood disorders and depression. These results confirm the importance of the survey in shedding light on isotretinoin side effects of this medication on the mental state along with mood disorders that may be associated to long-term use.

KEYWORDS: Survey, isotretinoin, oral administration, side effects.

INTRODUCTION:

Acne Vulgaris is an inflammatory Skin disease caused by changes in skin follicles and associated sebaceous glands, excessive secretion of oils from the glands in addition to accumulation of normal layer of dead skin cells close the follicles fat secretions under clogged pores. These factors give an environment suitable for the reproduction and activity of the anaerobic bacteria *propionibacterium acnes*, thus leading to skin irritation. It is necessary to accurately describe acne to choose the appropriate treatment and find out whether it is induced by genes, hormones or psychological effects.¹ Acne is treated by several drug methods. The first option is Benzoyl Peroxide for the treatment of mild acne because of its effectiveness and lack of side effects. Second is antibiotics both local antibiotics to treat light and moderate acne, and systemic antibiotics used in the case of moderate acne. Third is salicylic acid, azylic acid, hormones and topical and oral retinoids such as isotretinoin.²

Isotretinoin is 13-cis isomer of trans retinoic acid which is a derivative of vitamin A. This retinoid was synthesized in 1955, and was first used to treat psoriasis in Europe in 1973, then it was approved for the treatment of nodular acne in the United States since $1982.^3$

Isotretinoin is approved for the treatment of severe acne which is resistant to standard therapy. This medicament has been increasingly a popular treatment for acne vulgaris due to its high effectiveness.⁴ Although this good efficacy, isotretinoin is not completely safe. The oral administration of isotretinoin is contributed with a wide range of side effects such as dry mucous membranes, nose bleed, and dry skin, and the most important adverse effect of this drug is teratogenicity.^{5, 6} The objective of our study was to estimate the most common adverse effects of isotretinoin treatment among a sample of the Syrian youth by conducting a survey study on the use of Isotretinoin to increase the awareness among young adults of the medication's common side effects. There are limited studies about the awareness and concerns of acne patients about this drug, especially in Syria.

MATERIAL AND METHODS:

Sampling:

This survey was conducted at the faculty of Pharmacy, Al-Sham Private University as an observational study. We designed and published an electronic questionnaire directed to patients who were taking oral isotretinoin for at least two months. The questionnaire was sent to 370 individuals and we received responses from 320 participants (28 males and 292 females), during the period of two weeks. This questionnaire includes 20 questions divided into two parts, included questions about personal information (age, sex, weigh), questions about the medication (dosage, duration of medication and liver functions test) and questions about the common side effects of isotretinoin.

Data analysis:

The results of the questionnaire were arranged then statistically analyzed using SPSS program Ver. 25.

RESULTS:

Patients data:

Patients participated in the survey were 292 females (91.3%) and 28 males (8.8%) participated in the survey. We divided the participants into three age groups, and 186 participants aged between 20 and 30 years as detailed in table (1).

Age group	Percentage
15- 20 years	36.6%
21-30 years	58.1%
31 – 40 years	5.3%

Medication use data:

13.1% of all patients used isotretinoin for 3 months, 40% of all patients for 6 months,8.8% for 12 months and 1.5% for more than one year. A percentage of 91.6% of all participants took the medication under a doctor's prescription, while the rest 8.4% started the course without any prescription. This may be related to the high awareness of the studied community to take this drug under medical prescription.

We also found that only 144 of 320 (45%) participants had performed liver tests while the rest 176 (55%) didn't perform liver tests before taking the medication.

Drug side effects:

As a result of the survey we noticed that 19 participants out of 320 (5.3%) suffered from all the seven side effects. The most frequent side effect was chapped and dry lips (309 of 320 participants) 96.3% and secondly dermatoxerasia 81.6% with no significant relationship with age, gender or duration of drug administration. Also, 34.7% of all participants suffered from ophthalmoxerosis.

It was surprising that more than half of participants 55.6% suffered from mood disorders and depression, and 10% answered that they had suicidal tendencies. Table (2) summarizes the most frequent side effects with patients' percentages in the survey.

Table (2): The most frequent side effects with patients' percentages

Side effect	Number of patients	percentage
chapped and dry lips	308	96.3%
dermatoxerasia	261	81.6%
Depressive disorder	178	55.6%
Xeromycteria (Dry mucous membranes)	166	51.4%
Ophthalmoxerosis	111	34.7%
Menstrnal disorder	87	27.2%
Increase appetite	73	22.9%
Acroarthritis	60	18.7%
Anorexia	55	17.1%
Dizziness (vertigo)	50	15.6%
Anorthopia (night vision disorder)	47	14.6%
Stomachache	37	11.7%
Tendency to suicide	32	9.8%
Tachycardia (Accelerating heartbeat)	1	0.3%

DISCUSSION:

Our survey shows that only 5.3% had all the side effects together (19 out of 320 participants) which is relatively low. The most common side effect was chapped lips (96.3%), and this result is in correspondence with a previous Indian study where cheilitis was the most common observed adverse effect as a percentage of (98%) of all participants.⁶ In a previous Saudi study, dryness of the lips and face was on the top of isotretinoin side effects list (64.1%).⁷ And in another Saudi study, lips dryness percentage was approximately 68%.⁸

Mood disorders was relatively high after isotretinoin oral administration (55.6%) which is higher than the percentage found in a previous Saudi study where 39.1% of females complained from depression. The proportion of participants taking the drug without a medical prescription was relatively low (8.4%) which is lower than the proportion of the previous Saudi study where 94.1% of Saudi women took the medication without a medical prescription.⁸

On the other hand, the percentage of participants who took the drug without performing liver function tests was relatively high 55%.

CONCLUSION:

These results confirm the importance of shedding light on isotretinoin side effects and increasing the awareness of its possible complications, in addition to educate the patients about effects on the mental state along with mood disorders that may be associated to its long-term use.

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CONFLICT OF INTEREST:

The authors declare no conflict of interest.

REFERENCES:

- Gollnick HP, Zouboulis CC, Akamatsu H, Kurokawa I, Schulte A. Pathogenesis and pathognesis-related treatment of acne. J Dermatol. 1991;18:489–99.
- Sanjay K Rathi. ACNE VULGARIS TREATMENT: THE CURRENT SCENARIO. Indian J Dermatol. 2011 Jan-Feb; 56(1): 7–13.
- Diane K. Wysowski, Marilyn Pitts, Julie Beitz. An analysis of reports of depression and suicide in patients treated with isotretinoin. JAAD October 2001Volume 45, Issue 4, Pages 515– 519.
- Piotr Brzezinski, Katarzyna Borowska, Anca Chiriac, Janusz Smigielski. Adverse effects of isotretinoin: A large, retrospective review. Dermatologic Therapy. 2017;30: e12483.
- Borovaya, A., Dombrowski, Y., Zwicker, S., Olisova, O., Ruzicka, T., Wolf, R., et al. (2014). Isotretinoin therapy changes the expression of antimicrobial peptides in acne vulgaris. Archives of Dermatological Research ,306, 689–700.
- Parinitha Rao K, Ramesh Bhat M, Nandakishore B, Dandakeri S, Martis J, et al. (2014) Safety and efficacy of low-dose isotretinoin in the treatment of moderate to severe Acne vulgaris. Indian Journal Dermatology 59: 316
- Al-Harbi M. Concerns and Awareness of Acne Patients About Isotretinoin in Qassim Region of Saudi Arabia. Int J Health Sci (Qassim). 2010 Jan; 4(1): 47–51.
- Al-Suhaibani S. (2016) The Impact of Oral Isotretinoin Dryness and Depression on Saudi Women in Qassim Region: A Survey. J Depress Anxiety 5: 245. doi: 10.4172/2167-1044.1000245.