

Concerns and awareness of acne patients about Isotretinoin in Qassim region of Saudi Arabia

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Abstract

Background: Oral Isotretinoin is the most effective choice in the treatment of severe acne, it is the most widely prescribed teratogenic drug in the USA and Canada. Due to large number of its adverse effects and the necessity of long term use, patients have difficulties in complying with the treatment and some may refuse taking the drug.

Objectives: To assess knowledge, concerns and awareness of acne patients in Qassim region, Saudi Arabia, about Isotretinoin, including the factors that may affect compliance.

Subjects and Method: This non-interventional cross-sectional survey was conducted through distribution of questionnaires over two month's period from 8th May to 23rd July 2009 in acne patients from the Qassim region. The returned questionnaires were analyzed using SPSS version 17.0. The P <0.05 was accepted as cut-off point for statistical significance.

Results: Three hundred fifty six acne patients were included in the study, 57.6% were female and 42.3% were male; 76.7% knew about Isotretinoin and its uses, the main source of information (for both genders) was the physician, followed by other acne patients. Sixty three percent of subjects knew about the adverse effects of the drug. Dryness and teratogenicity were the most well-known adverse effects and 85.9% didn't have any objection in using the drug. Adverse effects followed by duration of the treatment were the top concerned issues. Out of those who were using the drug, dryness of the lips and face were the most disturbing adverse effects.

Conclusion: A majority of acne patients have the knowledge about Isotretinoin and its adverse effects. This study highlighted the importance of health education for better acceptance of this drug. Patients should be instructed about proper moisturization methods while using this drug.

Key words: Isotretinoin, Teratogenicity, Acne vulgaris, Adverse effects

Introduction

Oral isotretinoin is a vitamin A derivative, marketed as an oral treatment for the refractory severe acne cases and is considered the most effective choice in the treatment of such cases.[1] Isotretinoin is by far the most cost effective drug, when compared with other medications for treatment of severe and scarring acne, but has been shown to be teratogenic when used during pregnancy.[2] In recent years, it has also been used for mild to moderate forms of acne, hence increasing the likelihood of exposure to birth defects. Indeed, in a population-based study, 64% of first isotretinoin prescriptions were given to patients who did not have a history of other anti acne medication use.[3] Isotretinoin is used 90% of the time by people between 13 and 45 years of age[4] and 50% of isotretinoin prescriptions are for women.[3] It is the most widely prescribed teratogenic drug in the USA and Canada. Acne, especially in more severe forms, has the potential to result in scarring and permanent disfigurement.

Previous studies showed that combination therapies are a highly effective treatment in severe forms of acne. However, scarring can occur in patients with acne who had not responded to conventional antibiotic therapy and combination treatments.[4] This condition can cause significant embarrassment and anxiety specially among young people. Therefore, effective treatment is necessary to prevent significant psychological and social impairment in these patients. Application of isotretinoin to acne has been expanded to treat those patients with less severe but scarring acne who are responding unsatisfactorily to conventional therapies.[5] However, its use is associated with many side effects, some of which can result in very disastrous consequences. Recent reports indicate that acne patients can benefit from low dose or intermittent treatment protocols.

Low dose isotretinoin, such as 0.15–0.40 mg/kg was reported to be effective with a low incidence of severe side effects.[6] Strauss et al.[7] showed that single daily doses of 0.4 mg/kg of micronized isotretinoin is effective in patients with severe recalcitrant nodular acne with a lower risk of mucocutaneous events, and hypertriglyceridemia, than in those receiving standard doses of isotretinoin. Due to large number of side effects and the necessity of long-term daily use of isotretinoin, patients may have difficulty in complying with the treatment and some of them may refuse taking this drug. There are limited studies about the awareness and concerns of acne patients about this drug, especially in Saudi Arabia.

Objectives

To assess the knowledge, concerns and awareness of acne patients in Qassim region of Saudi Arabia about isotretinoin, including factors that may affect their compliance.

Subjects and Method

This non-interventional cross-sectional survey was conducted in the Qassim region over a period of two months from May to July 2009 using a self-administered questionnaire. The respondents were acne patients from Qassim region attending the outpatient clinics in King Fahad Specialist Hospital, Buraidah Central Hospital and Qassim University Medical Unit. After a review of previous related studies, a self-administered questionnaire was designed for a pilot study of 20 patients, visiting the King Fahad Hospital and minor adjustments were made for the full study. The questionnaire was designed in Arabic language and it contained 12 questions along with lists of possible answers. The respondents were asked to choose the most relevant response to each question. Part of the questionnaire was designed to be filled by those who used or were using Isotretinoin at the time of the study to elicit the side effects and its interference with daily life activities.

The data were collected in collaboration with residents' doctors and nurses who were working in dermatology clinics of the above-mentioned health facilities during the time of the study. Ethical approval for this study was obtained from the Medical Ethics Committee of the College of Medicine, Qassim University. The returned questionnaires were entered into a database and were analyzed using Statistical Program for Social Sciences for Windows (SPSS release 17.0). The *P* value of 0.05 or lower was accepted for statistical significance for all statistical tests.

Results

Three hundred fifty six patients completed the survey; 205 (57.6%) were females and 150 (42.4%) were males. The mean age of respondents was 23.6 ± 5.8 , we surveyed a relatively educated population, 51.4 % of them being in the university, as shown in table 1. Two hundred seventy three subjects (76.7%) claimed that they had information about isotretinoin; out of those who knew about isotretinoin, 159 (58.2%) were female and 114 (41.8%) were male but the difference was not statistically significant ($P=0.68$). The sources of information were diverse: the commonest source of information for

both male and female patients was their doctors, followed by other acne patients, as shown in table 2. Table 3 shows that 216 (63.2%) of those who completed the survey knew that this drug carried a number of side effects; there was no statistically significant gender difference ($P=0.62$). Dryness was the most well known side effect followed by teratogenicity, for both males and females. Two hundred and ninety two (85.9%) of those who completed the survey said that they do not have any objection to start using this drug. However, males were less ready to use isotretinoin and there was significant statistical difference between the genders regarding their readiness to start using isotretinoin ($P=0.001$). Out of those who were ready to use the drug, fear of the adverse effects was the most common concern, followed by the duration of treatment. Teratogenicity was among the least concerns as shown in table 4. Among the participants, 21.1% were using the drug at the time of the survey, out of them 63.7% reported that they have side effects which interfere with their daily life, there was statistically significant gender deference ($P=0.013$) regarding side effects that interfered with daily activity. Dryness of the lips and face was on the top of list (64.1%) followed by xerosis (15.6%) but there were no significant gender differences ($P=0.25$) as shown in table 5.

Table 1 – Demographic Data

Variable	No. (%)
S Mean (Age_+ SD)	23.57±5.8_+
Male	151 (42.4)
Female	205 (57.6)
Single	283 (79.5)
Married	73 (20.5)
Educational status	
University	183 (51.4)
High school	111 (31.2)
Intermediate	45 (12.6)
Primary or less	17 (4.8)

Table 2 – Knowledge of Isotretinoin

Studied parameter	Total	Male	Female	P value
	N (%)	N (%)	N (%)	
Do you know about (drug)?	345 (100)	146 (42.3)	199 (57.7)	
YES	273(76.7)	114 (41.8)	159 (58.2)	0.68
NO	72 (20.9)	32 (44.4)	40 (55.6)	
Source of information*	273 (100)	114 (41.8)	159 (58.2)	
Doctors	169 (61.9)	57 (33.7)	112 (66.3)	
Previous pt.	38 (13.9)	27 (71.1)	11 (28.9)	
Friends	24 (8.9)	14 (58.3)	10 (41.7)	
Internet	22 (8.1)	7 (31.8)	15 (68.2)	0.00
The family	7 (2.6)	2 (28.6)	5 (71.4)	
Newspaper	7 (2.6)	4 (57.1)	3 (42.8)	
Pharmacist	6 (2.2)	4 (66.7)	2 (33.3)	

* Only for participants who answered yes to above question (N=273)

Table 3 - Awareness about side effects of Isotretinoin

Studied parameter	Total N (%)	Male N (%)	Female N (%)	P
Do you know side effects of the drug	342 (100)	144 (42)	197 (58)	
YES	216 (63.2)	99 (45.8)	116 (53.7)	0.62
NO	126 (36.8)	45 (35.7)	81 (64.3)	
What is the side effect that you know*	216 (63.2)	99 (45.8)	116 (53.7)	
Dryness	118 (54.6)	57(48.3)	61 (51.7)	
Teratogenicity	61 (28.2)	18(29.5)	43 (70.5)	
Lipid profile disturbance	20 (9.3)	12(60)	8 (40)	
Constipation	14 (6.5)	9 (64.3)	6 (35.7)	0.01
Depression	3 (1.4)	1 (33.3)	2 (66.7)	

* Includes only those participants who answered yes to above question (N=216)

Table 4- Patients willingness to start using the drug and their concerns

Studied parameter	Total N (%)	Male N (%)	Female N (%)	P
Ready to use the drug	341 (100)	142 (42)	198 (58)	
YES	292 (85.9)	111(38)	181 (62)	0.001
NO	45 (13.2)	28 (62)	17 (38)	
Concerns before starting the drug	292 (85.9)	111 (38)	181 (62)	
Side effects	160 (54.8)	60 (37.5)	100 (62.5)	
The duration	104 (35.6)	56 (53.8)	48 (46.2)	0.001
Teratogenicity	28 (9.6)	0	28 (100)	

Table 5 - Patients experience with the drug

Studied parameter	Total	Male	Female	P
	N (%)	N (%)	N (%)	
Are you using this drug?				
YES	71 (21.1)	29 (40.8)	42 (59.2)	0.87
No	265 (78.9)	105 (40)	159 (60)	
Did you have side effects that interfere with daily activity				
YES	167 (63.7)	81 (49)	86 (61)	0.01
NO	95 (36.3)	31 (33)	64 (67)	
What is the most bothering side effect *				
Dryness of face and lips	107 (64.1)	42 (39.3)	65 (60.8)	
Xerosis	26 (15.6)	9 (34.6)	17 (65.4)	0.25
Constipation	20 (12)	12 (60)	8 (40)	
Joint pain	14 (8.4)	5 (35.7)	9 (64.3)	

* Includes only those participants who answered yes to above question (N=167)

Discussion

Although many of acne patients know about this drug in one way or other, some might hesitate or even scared to start using this drug, due to lack of accurate information about the drug. It has been shown by previous studies that good understanding and awareness of the patients about this drug helps in increasing compliance and minimize adverse effects. This is the first survey in Qassim region which was aimed to assess the perception and concerns of acne patients about Isotretinoin. Most of the participants were educated and 76.7% of them had some information about this drug and its side effects. One of the most well known side effects is dryness of the face and lips, followed by teratogenicity. A majority of participants got information from their doctors, which highlights the role of the doctors as providers of health education. A majority of those who were involved in this survey (85.9%) showed acceptance to start using this drug although 54.8% were afraid of its side effects. An important observation in our study was that only 9.6% respondents (all of them females) were concerned about birth defects, which should alarm the doctors to concentrate on providing education about the teratogenic effects when prescribing this drug for female patients. A little over one fifth of respondents were using this drug at the time of the study. A majority of them suffered from dryness of face and lips, indicating that doctors should concentrate on educating their patients about use of moisturizers while using this drug.

Conclusion

This was the first population-based study of knowledge and concerns of acne patients about isotretinoin in the Qassim regions, which showed that acne patients are aware about isotretinoin and its side effects and that the treating physician (mainly dermatologists) provide knowledge about this drug. Some patients also receive information from other acne patients. A majority of patients, however, do not know how to deal appropriately with the side effects. More time should be spent to

educate patients about how to avoid and deal with side effects of isotretinoin concentrating on explanation of common side effects, appropriate methods and frequency of moisturization by using creams and lotions in addition to other moisturizing methods. Female patients must always be clearly informed about the teratogenic effects of this drug, the appropriate methods of contraception and how long they should avoid pregnancy after completing their treatment courses should also be highlighted.

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References

1. Layton AM, Dreno B, Gollnick HP, Zouboulis CC. A review of the European Directive for prescribing systemic isotretinoin for acne vulgaris. *J Eur Acad Dermatol Venereol.* 2006;20:773–76.
2. Holmes SC, Bankowska U, Mackie RM. The prescription of isotretinoin to women: is every precaution taken? *Br J Dermatol.* 1998; 138:450–55.
3. Azoulay L, Oraichi D, Bérard A. Patterns and utilization of isotretinoin from 1984 to 2003: is there need for concern? *Eur J Clin Pharmacol.* 2006; 62: 667–74.
4. Gollnick HP, Graupe K, Zaumseil RP. Comparison of combined azelaic acid cream plus oral minocycline with oral isotretinoin in severe acne. *Eur J Dermatol.* 2001;11:538–44.
5. Goulden V, Clark SM, Mcgeown C, Cunliffe WJ. Treatment of acne with intermittent isotretinoin. *Br J Dermatol.* 1997; 137:106–8.

6. Amichai B, Shemer A, Grunwald MH. Low-dose isotretinoin in the treatment of acne vulgaris. *J Am Acad Dermatol.* 2006;54:644–46.
7. Strauss JS, Leyden JJ, Lucky AW, Lookingbill DP, Drake LA, Hanifin JM, et al. Safety of a new micronized formulation of isotretinoin in patients with severe recalcitrant nodular acne: A randomized trial comparing micronized isotretinoin with standard isotretinoin. *J Am Acad Dermatol.* 2001;45:196–207.
8. Al Robaee AA. Prevalence, knowledge, beliefs and psychosocial impact of acne in University students in Central Saudi Arabia. *Saudi Med J.* 2005;26:1958- 61.
9. Dai WS, LaBraico JM, Stern RS. Epidemiology of isotretinoin exposure during pregnancy. *J Am Acad Dermatol.* 1992;26:599-606.
10. Wysowski DK, Beitz J. "Methodological limitations of the study "isotretinoin use and risk of depression, psychotic symptoms, suicide, and attempted suicide." *Arch Dermatol.* 2001;137(8):1102-3.
11. Ferahbas A, Turan MT, Esel E, Utas S, Kutlugun C, Kilic CG. "A pilot study evaluating anxiety and depressive scores in acne patients treated with isotretinoin." *J Dermatol Treat.* 2004; 15(3):153-7.
12. Chren MM, Lasek RJ, Sahay AP, Sands LP. Measurement properties of Skindex-16: a brief quality of life measurement for patients with skin disease. *J Cutan Med Surg.* 2001; 5:105-10.
13. Hill-Beuf A, Porter JD. Children coping with impaired appearance. Social and psychological influences. *Gen Hosp Psychiatry.* 1984;6:294-301.
14. Moskop JC, Smith ML, De Ville K. Ethical aspects of teratogenic medications: the case of isotretinoin. *J Clin Ethics.* 1997;8:264–78.