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RESEARCH ARTICLE

PUBLIC USAGE OF ISOTRETINOIN IN SAUDI ARABIA: AN ONLINE SURVEY.

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Abstract

Isotretinoin (Roaccutane) is an effective medication for acne treatment. It has side effects and the main concern is its teratogenic effect. It has to be prescribed and followed up by dermatologists. In this study the public use of this medication is explored through an online questionnaire. Out of 401 respondents, 154 have used Roaccutane. Thirty one respondents have used it without medical consultation. These included females of childbearing age. Sources of recommendation of medication included pharmacists, friends, relatives and others. This warrants more rigorous restriction on its dispensing and public awareness efforts.

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Introduction:-

Acne vulgaris is a very common skin disease experienced mainly by adolescents and can have a substantial impact on quality of life. Early and effective acne treatment can prevent or minimize such complications. Oral isotretinoin is an effective modality for the treatment of severe acne (Gollnick HP et al., 2014).

Since its FDA approval on 1982, isotretinoin is becoming widely used to treat acne and actually, it is also used for milder acne that is resistant to other treatments or associated with significant scarring. The risk for adverse effects, including teratogenicity, precludes the use of this drug as routine acne therapy (Lammer EJ et al., 1985). Additionally, although the risks of other side effects are not very high, there is a need for careful monitoring by dermatologists. Earlier guidelines were published to guide the usage of this medication (Cunliffe WJ et al., 1997). Few changes were made to these guidelines later such as European Evidence-based (S3) Guidelines for the Treatment of Acne (Nast A et al., 2012). Teratogenicity is a major issue. The regulation on its dispensing is restricted in some countries and a special program is a prerequisite for its dispensing such as pregnancy prevention program registry (BAD guidelines) and iPLEDGE program (US food and Drug administration). The goals of these systems are to prevent fetal exposure to isotretinoin. (US food and Drug administration). Teratogenicity is the major concern for its inappropriate use and the other side effects are usually mild and manageable. Still it should be prescribed and monitored by dermatologists.

Previous study showed some redundancy in the dermatologist adherence to recommendations regarding isotretinoin prescription to females of childbearing potentials (AlGhamdi KM et al., 2011). Additionally, it has been shown that isotretinoin can be purchased online with little or no restriction (Lagan BM et al., 2014)

In Saudi, this medication can not be purchased from the pharmacy without medical prescription. But no regulation on the prescribing physician status and sometimes can be supplied from some pharmacies without prescription. It

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was noticed lately that some patients were taking this medication without prescription (Alrwisan AA et al., 2014), or the medication was advocated by pharmacists or some family members.

The aim of this study is to explore isotretinoin (Roaccutane as the main and widely known brand) use among acne patients without dermatologist supervision at Saudi Arabia. To our knowledge this is the first study of its kind in Saudi Arabia.

Methods:-

This is a non-interventional cross-sectional survey. It was conducted through distribution of online questionnaires over one month at August 2016 directed to acne sufferers from all regions of Saudi Arabia through social Medias.

The questionnaire was broadly divided into 3 categories of demographics, Anthropometry measures and Roaccutane using information. First part contained socio-demographic variables (age, gender, educational level and place of residency). Second part consisted of 2 items, height and weight to allow for the calculation of body mass index of patients. Third part contained 10 questions and provided details about Roaccutane usage. It included a question of whether he/ she have ever suffered from acne, if he/ she have visited a dermatologist for this problem, and if he/ she have used Roaccutane and if yes, if he/ she had a dermatologist consultation before using the medication. Sources of advice of using Roaccutane if not dermatologist (pharmacist, relatives, friends, website, or others). Additional questions about the dose (10mg daily, 20mg daily, more than 20mg daily, unknown), effectiveness of Roaccutane (yes, no), appearance of side effect (yes, no) and the side effects (dryness, headache, abdominal pain, blurring of vision or any other side effects).

The returned questionnaires entered into a database and analyzed by using SPSS version 22.

Results:-

In total 401 responded to the questionnaire. Of those 320 suffered from acne. These were included for further analysis, of which 238 (74.4%) were female and 82 (25.6%) were male. The majority was from the age group of 20-30 years and 268 (83.8%) had university educational level. The mean score of BMI was 23.6 ± 4.5 (range 14-39) (Table 1).

The majority of the participants reported started having acne at the age of 14-20 years. More than half (52.2%) visited dermatologist.

A total of 154 (48.1%) used Roaccutane. Ten mg per day was used by 7 subjects (4.6%), 20 mg/day and more than 20 mg/day were used by 59 subjects each (38.3 %) and the dose was unknown in 29 subjects (18.8%). The most common side effect was dryness (76.2%) (Table 2)

Thirty one subjects used Roaccutane without medical consultation (9.69% of study subjects). The characteristics of this group is presented in table 3.

Discussion:-

This study's aim is to explore isotretinoin (Roaccutane as the main and widely known brand) use among acne patients without dermatologist supervision at Saudi Arabia. To our knowledge this is the first study of its kind in Saudi Arabia. In this study nearly 10% (31 cases) acne sufferers reported using Roaccutane by advice from other than doctors. Females (14 cases) constituted 45% of them. They were mainly from the age group of 20-30 years. More than third of them used the medication with doses of more than 20 mg. They were advised to use Roaccutane by pharmacists, friends, relatives and others.

These results indicate the feasibility of using the medication without proper medical supervision and the lack of public awareness of its requirements. Teratogenicity is a major concern in using this medication and as mentioned earlier; females in the childbearing age has used it without medical consultation.

Although a recent meta-analysis (Lee YH et al., 2016) of the effect of isotretinoin on the laboratory changes suggest that monthly laboratory monitoring is not needed, there should be at least a baseline investigations. Apart from mucocutaneous side effects other side effects are not common. Other side effects can be encountered by patients

rarely as intracranial hypertension. This is supposed to be a medical emergency. In case the patient is using this without prescription it might not be mentioned in case of any complaint and could be missed as a cause of the problem.

Study limitation include the nature of the study, being a web based study. So, it might not be very representative. Nevertheless, it demonstrates the accessibility of Isotretinoin with a possible consequences of side effects specially the teratogenicity if used by pregnant females.

In conclusion considerable number of acne patients used isotretinoin without medical prescription which warrants more vigorous restriction on its dispensing and need for public awareness efforts to prevent critical side effects of the medication.

Table (1):- Demographics and characteristics of the study population:

Variables		N= 320	%
Age (years)			
	Less than 20	56	17.5
	20-30	242	75.6
	30-40	21	6.6
	Above 40	1	.3
Gender			
	Male	82	25.6
	Female	238	74.4
Educational level			
	Intermediate	4	1.3
	High school	48	15.0
	University	268	83.8
Age of appearance of acne			
	14-20	259	80.9
	21-30	44	13.8
	31-40	2	0.6
	unknown	15	4.7
Consultation of dermatologist			
	Yes	167	52.2
	No	92	28.8
	Not applicable	61	19.0
Use of Roaccutane			
	Yes	154	48.1
	No	149	46.6
	Unknown	17	5.3

Table (2):- Characteristics of Roaccutane users:

Variables		N = 154	%
Had a medical consultation before using Roaccutane			
	Yes	143	93.5
	No	11	6.5
Dose of Roaccutane			
	10 mg	7	4.6
	20 mg	59	38.3
	More than 20 mg	59	38.3
	Unknown	29	18.8
Side effects of Roaccutane			
	Dryness	121	78.6
	Headache	2	1.3
	Vision	3	1.9

	Abdominal pain	2	1.3
	Others	7	4.5
	unknown	19	12.3

Table (3):- Characteristics of Roaccutane users who had prescription from other than doctors:

Variables		N = 31	%
Age:			
	Less than 20	8	25.8
	20-30	20	64.5
	31-40	3	9.7
Gender:			
	Male	17	54.8
	Female	14	45.2
Source of advice:			
	Pharmacist	10	6.5
	Friend	4	2.6
	Relative	5	3.2
	Web	1	.7
	Others	11	7.1
Dose:			
	10 mg	3	9.7
	20 mg	8	25.8
	More than 20 mg	11	35.5
	Unknown	9	29.0

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