Awareness of Taibah University Female Students Toward Risks and Safety of Using Oral Isotretinoin for Acne Treatment

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Abstract

Background & Objectives: Isotretinoin is considered to be the most effective medication in treatment of refractory severe acne especially with scarring. In recent years, its application has been extended to those patients with mild to moderate acne despite being associated with many serious side effects. The objective of this study was to assess the awareness of female students in Taibah University, Medina, Saudi Arabia about oral isotretinoin therapy and the adverse events, risks and safety issues related to its use.

Methods: A cross-sectional study was carried out at the female section of both colleges of Medicine and Nursing, Taibah University, Medina, Saudi Arabia, using a self-administered, semi-structured validated questionnaire that included questions on socio-demographic information, knowledge of students about oral isotretinoin therapy and adverse effects, risks, safety issues and precautions related to its use.

Results: Two hundred and twenty-two students (27%) responded to the questionnaire. Dryness was the most well-known side effect (65.3%) followed by hepatic side effects (50%) and teratogenicity (37.3%). Most participants knew that pregnant women, breastfeeding women, women with childbearing potential and children (65.3%, 46%, 30.7% and 30%, respectively) were the most at risk patients for side effects of isotretinoin. Out of those who knew isotretinoin, 78% reported that they do not know the safety issues and precautions.

Interpretation & Conclusions: The total awareness level toward isotretinoin is unsatisfactory among medical and nursing female students, which attracts attention for educational and awareness programs to improve their knowledge.

Key words: Acne, awareness level, female, isotretinoin, risk, safety, Taibah University

Introduction

Acne is a chronic inflammatory disease, which has a significant psychological and social impact. Most cases of acne present with a pleomorphic variety of lesions consisting of comedones, papules, pustules and nodules, and in some cases are accompanied by scarring (1).

The initial event in the development of an acne lesion is abnormal desquamation of the keratinocytes that line the sebaceous follicle and create a microplug or microcomedo. In addition, the increase in circulating androgens at the onset of puberty stimulates the production of sebum into the pilosebaceous unit. These events combine to create an environment within the pilosebaceous unit that is favourable for the colonization of the commensal bacteria, Propionibacterium acnes (2).

Isotretinoin noticeably reduces the production of sebum and shrinks the sebaceous glands. It stabilizes keratinization and prevents comedones from forming and reduces inflammation in moderate to severe inflammatory acne. The exact mechanism of action is unknown; however, it is known that it alters DNA transcription (3).

Isotretinoin is considered to be the most effective medication in the treatment of refractory severe acne cases especially with scarring; however, its use is associated with many serious side effects. One of the most important and significant issues is its teratogenic effect when used during pregnancy (2).

Moreover, isotretinoin use has been associated with psychiatric side effects. There have been a growing number of reported cases of the following side effects: depression, suicide, aggression, psychosis, mood swings, violent behaviour, hostility, bipolar disorder and obsessive-compulsive disorder (5).

Some studies have shown that isotretinoin could affect liver enzymes and lipid levels (3). It may increase serum levels of liver enzymes, triglycerides (TGs) and low-density lipoprotein (LDL) cholesterol and reduce the level of high-density lipoprotein (HDL) cholesterol(6).

Because of all of these significant side effects, patients should be monitored during the course of the treatment to detect these abnormalities before they become clinically significant; however, the frequency of testing varies in clinical practice owing to a lack of consensus (7).

In contrast, multiple prior studies have concluded that only baseline fasting lipid and hepatic panels with one follow-up test are necessary, (8) and one of these studies found that most blood abnormalities occur within the first 2 months of therapy (9).

In recent years, application of isotretinoin has been extended to those patients with mild to moderate forms of acne, especially to those who are responding unsatisfactorily to conventional therapies, hence increasing the likelihood of exposure to birth defects and other disorders.

Isotretinoin is used 90% of the time by people between the ages of 13 and 45 years, (4) and 50% of isotretinoin prescriptions are for women as reported by previous studies (5). There are limited research studies about the awareness of the adverse effects and safety issues in using isotretinoin therapy, especially in Saudi Arabia despite its wide use for acne treatment. Therefore, the aim of the conduction of this study was to highlight and give the overview of this rising issue with the following objective:

To assess the awareness of female students in Taibah University, Medina, Saudi Arabia about oral isotretinoin therapy and the adverse events, risks and safety issues related to its use.

Material and methods

Study design and setting:
A cross-sectional study was carried out at the female section of two colleges (Faculty of Medicine and Faculty of Nursing), Taibah University, Medina, Saudi Arabia.

Study population and study period:
Undergraduate medical and nursing female students in Taibah University during their study period in the academic year 2017-2018 were invited to participate in the study.

Sampling technique and size:
All the undergraduate female students of all years of both the selected colleges were invited to participate in the study.

Data collection tools and procedures:
The data were collected using a self-administered, semi-structured questionnaire developed by the researchers after extensive review of the literature and similar studies, and then distributed to the participants through email through the leader of each year. The questionnaire consisted of four parts:

First part: included questions on socio-demographic information of the participants such as age, residence (e.g. urban or rural), marital status, college (medicine or nursing), class level/year in university etc.
Second part: included questions on knowledge and awareness of students about oral isotretinoin therapy known commercially as Roaccutane/Accutane and the risks and adverse effects related to its use.
Third part: included questions on knowledge and awareness of students toward safety issues and precautions related to the use of isotretinoin.
Fourth part: included questions to be filled in by those who had used or were using isotretinoin at the time of the study to elicit information about the side effects and determine whether they received counselling before its use.

Scoring of knowledge:
Each question was scored 0-1 for awareness. Total score was 26. If the student score was <13, her knowledge was considered unsatisfactory (poor level of awareness), and if her score was ≥13, her knowledge was considered satisfactory (good level of awareness).

Pilot study:
Before the start of the study, the semi-structured questionnaire was pre-tested on 10 students to explore if there was any ambiguity or items leading to misunderstanding in the questionnaire in order to reach its current final form. These 10 students were not included in the main survey.

Validity and reliability of the questionnaire:
The items in the questionnaire were obtained from a number of validated questionnaires, (6, 7,8,9) and validity was completed by reviewing it with 3 experts. The questionnaire was re-administered after a week to the same sample of the pilot study to check test–retest reliability.

Data management:
Data were coded, entered and analysed using the Statistical Package for Social Science (SPSS) version 21.0 (SPSS, Chicago, IL, USA). Quantitative data were represented as the mean and standard deviation, and qualitative data were represented as frequencies and percentages.

Ethical approval:
Official permission was obtained from the Taibah University Scientific Ethical Committee. Informed consent was obtained from all the participants after describing the aim of the study. Privacy and confidentiality were assured.

Funding: Self-funded.

Abbreviations

PEP	**Personal Excellence Pathway**	IL	Illinois
DNA	Deoxyribonucleic acid	USA	United States of America
TGs	Triglycerides	SD	Standard deviation
LDL	Low-density lipoprotein	PPP	Pregnancy Prevention Program
HDL	High-density lipoprotein	FDA	Food and Drug Administration
SPSS	Statistical Package for Social Science	KSA	Kingdom of Saudi Arabia

Results

Table 1: Socio-Demographic Characteristics of the Studied Subjects

	Frequency (n=222)	Percentage (%)
Age (years):	Mean ± SD 22.46 ± 3.71	
College:		
Medicine	126	56.8
Nursing	96	43.2
Academic year:		
First	43	19.4
Second	49	22.1
Third	45	20.3
Fourth	59	26.6
Fifth	26	11.7
Marital status:		
Unmarried	193	86.9
Married	29	13.1
Residence:		
Rural	25	11.3
Urban	197	88.7

The overall number of participants was 222 female students with a response rate of 27% (222/827) from the college of medicine (56.8%) and nursing (43.2%) in Taibah University with a mean (SD) age of 22.46 ± 3.71 years. About 26.6% of the students were from the fourth year, 22.1% from the second year, 20.3% from the third year, 19.4% from the first year and 11.7% from the fifth year. Regarding marital status, 86.9% of the participants were unmarried and 13.1% were married, with the majority (88.7%) living in an urban residence compared to 11.3% living in rural areas (Table 1).

Figure 1: Percentage of Respondents According to Their Knowledge about Isotretinoin Therapy for Acne

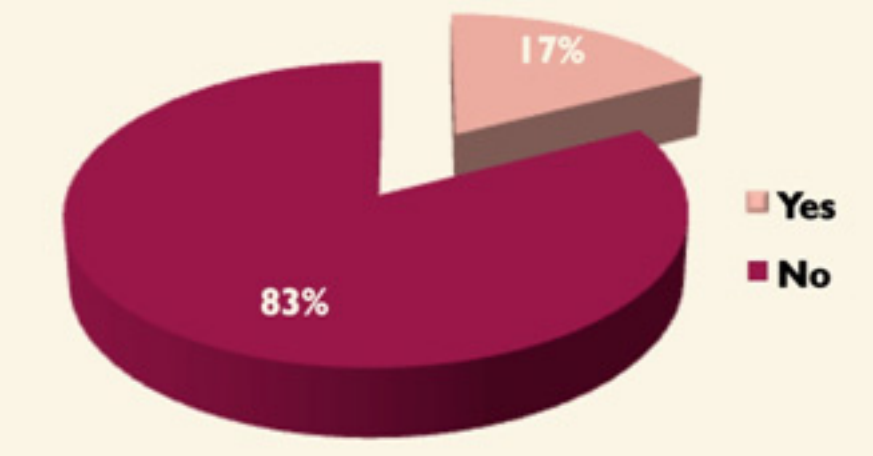
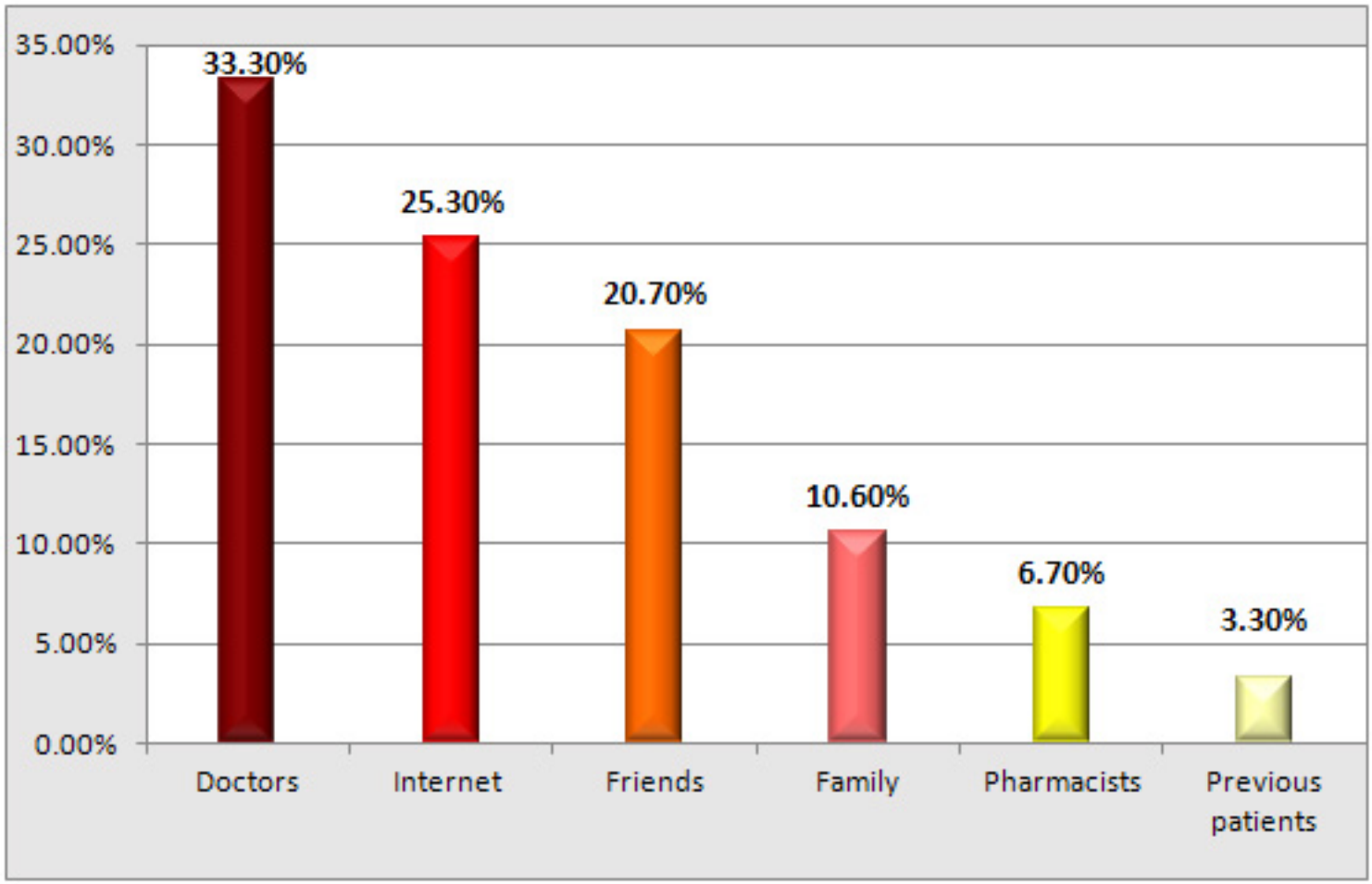


Figure 1 shows that more than half of the female medical students (67.6%) knew about the oral isotretinoin therapy for acne. (n = 150).

Figure 2: Sources of Information of Isotretinoin Therapy for Acne



From those who mentioned that they had information about isotretinoin therapy for acne, their commonest sources of information were from doctors (33.3%) followed by the Internet (25.3%), friends (20.7%), family (10.6%), pharmacists (6.7%) and previous acne patients (3.3%), as shown in Figure 2.

Table 2: Knowledge about Side Effects of Isotretinoin and at risk Patients

	Frequency (n=150)	Percentage (%)
What are the risks and side effects of using oral isotretinoin drug?		
Teratogenicity		
Know	56	37.3
Don't know	94	62.7
Dryness		
Know	98	65.3
Don't know	52	34.7
Constipation		
Know	40	26.7
Don't know	110	73.3
Lipid profile disturbance		
Know	45	30.0
Don't know	105	70.0
Hepatic side effect		
Know	75	50.0
Don't know	75	50.0
Depression		
Know	45	30.0
Don't know	105	70.0
Anaemia		
Know	11	7.30
Don't know	139	92.7
Back ache, bone pain and arthralgia		
Know	2	1.30
Don't know	148	98.7
Who are the at-risk patient groups for using isotretinoin?		
Pregnant women		
Know	98	65.3
Don't know	52	34.7
Breastfeeding women		
Know	69	46.0
Don't know	81	54.0
Women with childbearing potential		
Know	46	30.7
Don't know	104	69.3
Children		
Know	45	30.0
Don't know	105	70.0
Elderly		
Know	17	11.3
Don't know	133	88.7
Adults		
Know	3	2.00
Don't know	147	98.0

Regarding awareness level of participants about the side effects of isotretinoin and at risk patients, dryness was the most well-known side effect (65.3%) followed by hepatic side effects (50%) and teratogenicity (37.3%). Most of the participants knew that pregnant women, breastfeeding women, women with childbearing potential and children (65.3%, 46%, 30.7% and 30%, respectively) were the most at risk patients for side effects of isotretinoin, as shown in Table 2.

Table 3: Awareness of Safety Issues and Precautions for Using Oral Isotretinoin

	Frequency (n=150)	Percentage (%)
Use of contraception for married women		
Know	55	36.7
Don't know	95	63.3
Regular specific investigation for follow-up		
Know	80	53.3
Don't know	70	46.7
Avoid exposure to sunlight and use of sun protection		
Know	68	45.3
Don't know	82	54.7
Avoid taking drugs without medical counselling		
Know	54	36.0
Don't know	96	64.0
Avoid blood donation during therapy		
Know	25	16.7
Don't know	125	83.3
Avoid laser treatments for a period of 1 year		
Know	39	26.0
Don't know	111	74.0
Contraindicated in patients allergic to peanuts or soya		
Know	14	9.33
Don't know	136	90.7
Not to take vitamin supplements containing Vitamin A during oral isotretinoin therapy		
Know	20	13.3
Don't know	130	86.7

Table 3 shows that out of those who knew the drug, 78% reported that they did not know the safety issues and precautions for using oral isotretinoin. Meanwhile, regular specific investigation for follow-up, avoiding exposure to sunlight, use of contraception for married women and avoid taking drugs without medical counselling were the known safety issues and precautions by most of the participants (53.3%, 45.3%, 36.7% and 36%, respectively).

One hundred and three students (68.7%) out of those who knew the drug mentioned that they did not know of the required regular investigations during treatment with isotretinoin, while liver function tests, kidney function tests, lipid profiles, complete blood count and pregnancy test were known as the required regular investigations during treatment with isotretinoin by most of the participants (65.3%, 42.7%, 36.7%, 41.3% and 36%, respectively), as shown in Table 4.

Figure 3 shows that more than half of the female medical students (62.16%) did not use oral isotretinoin, while 37.84% of participants were using oral isotretinoin.

Forty-seven (56.0%) of the current students who used oral isotretinoin therapy for acne received counselling before they started using the drug, while 27 students (32.1%) developed sides effects during the use of oral isotretinoin therapy, as shown in Table 5.

Figure 4 shows the total awareness level of female students in Taibah University, Medina, Saudi Arabia toward oral isotretinoin therapy and the adverse events, risks and safety issues related to its use. The majority of the participants (84.7%) had an unsatisfactory level of awareness compared to 15.3% who had satisfactory awareness level.

Table 4: Awareness of the Required Regular Investigations During Treatment With Isotretinoin

	Frequency (n=150)	Percentage (%)
Liver function tests		
Know	98	65.3
Don't Know	52	34.7
Kidney function tests		
Know	64	42.7
Don't Know	86	57.3
Lipid profiles		
Know	55	36.7
Don't Know	95	63.3
Complete blood count		
Know	62	41.3
Don't Know	88	58.7
Pregnancy test		
Know	54	36.0
Don't Know	96	64.0

Figure 3: Usage Percent of Isotretinoin Drug Between Participants

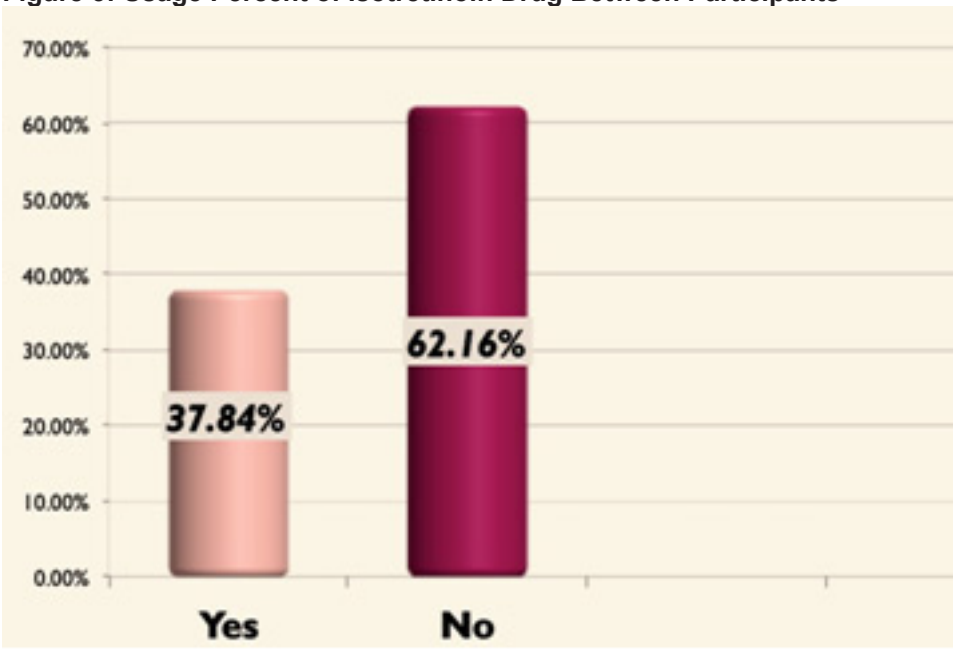
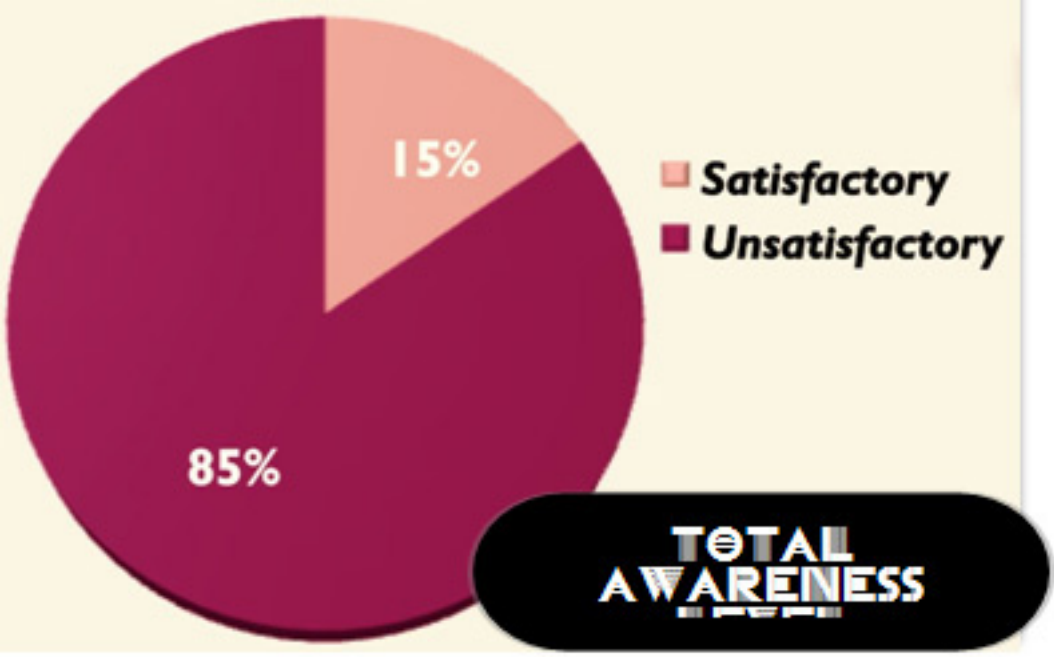


Table 5:Drug Experience of Current Students Using Oral Isotretinoin Therapy

	Frequency (n=84)	Percentage (%)
Did you receive any counselling before you started using oral isotretinoin therapy?		
Yes	47	56.0
No	37	44.0
Did you develop any side effects during its use?		
Yes	27	32.1
No	57	67.9

Figure 4: Total Awareness Toward Oral Isotretinoin Therapy for Acne Among Participants



Discussion

Isotretinoin, known commercially as Roaccutane/Accutane is an effective medication for the treatment of severe recalcitrant acne. Although many people know or even use isotretinoin drug, some of them do not have enough information about this drug. Others may even fear using this drug because of the lack of accurate information about the drug. (10) Previous research studies have shown that good knowledge and awareness about the drug increases the compliance and decreases the side effects(10).

This was the first study in Taibah University, Medina, Saudi Arabia, which aimed to assess the awareness of female students about oral isotretinoin therapy. The present study shows that more than half of the female medical students (67.6 %) had some information about the oral isotretinoin therapy for acne, and their major sources of information were from doctors, which is consistent with a study conducted by Al-Harbi, 2010 at Qassim region, (10) which clarifies the role of the doctors as providers of health education.

Dryness was one of the most well-known side effects in our study (65.3%) followed by hepatic side effects (50%) and teratogenicity (37.3%). This result is in agreement with that of similar previous studies that have shown dryness of lips, eyes and skin as the most common side effect among patients who used isotretinoin, (11) indicating the importance of educating patients about the drug side effect and the ways to reduce this side effect.

The regulatory authority in each country has approved a Pregnancy Prevention Program (PPP), which consists of advice on education, therapy management and control of distribution of the drug(12). According to this program, women of childbearing potential should use at least one method of effective contraception, preferably two forms, starting one month before and finishing one month after the course of isotretinoin treatment(13). In order to achieve safety and risk reduction of isotretinoin therapy, a program was created in 2006 by the United States Food and Drug Administration (FDA) and directed at women of childbearing potential. This program states that isotretinoin drug can be prescribed only to those female patients who meet the program criteria for pregnancy prevention before and during the use of isotretinoin drug(14, 15). In agreement with these precautions, most of our participants were aware that pregnant women, breastfeeding women, women with childbearing potential and children (65.3%, 46%, 30.7% and 30%, respectively) were the most at risk patients for side effects of isotretinoin. Similarly, a study done by Lammer et al.(16) has shown that there was 25-fold increased risk of birth defect among babies of women who were exposed to isotretinoin during pregnancy than those who were not exposed to isotretinoin during pregnancy. Another study done by Lewicka et al.(13) has shown that the majority of women (94.2%) were aware of the risk of serious foetal malformation during isotretinoin treatment and (39.3%) was instructed to perform a pregnancy test at home before isotretinoin administration, which highlights the importance of proper counselling about pregnancy prevention programs in minimizing birth defects among women of childbearing age in the course of treatment.

There are many issues and precautions that should be taken when using oral isotretinoin. This study mentions that nearly half of the participants (45.33%) were aware about the importance of avoiding exposure to sunlight while they were on treatment and using sun protection, while few of our participants knew about the need to avoid blood donation and taking Vitamin A during therapy. In addition, only 9.33% knew that this drug is contraindicated in patients allergic to peanuts or soya.

Indeed, isotretinoin may increase the sensitivity of the skin to light, so the use of sun protection is important during treatment. Several studies have reported that people who use isotretinoin therapy should avoid blood donation while taking the drug and 1 month after, as it is a teratogenic drug and may cause birth defects if given to a pregnant woman (17,18). In addition, previous reports have demonstrated that supplements containing Vitamin A should not be used with isotretinoin to avoid additive toxic effects (12).

Cosmetic procedures such as waxing and laser can increase the chance of scarring if used during the period of treatment. However, there is insufficient evidence to justify delaying cosmetic procedures such as waxing and laser for patients currently or recently using isotretinoin(4). Those patients who have allergy to soya and peanuts should inform their doctor and pharmacist before starting the treatment because isotretinoin contains soya oil. However, in 2015, N.M.K. et al. reported that he had treated six patients with known severe peanut allergies with isotretinoin without any anaphylactic reaction(19).

As regards the required investigation during oral isotretinoin therapy, our results show that 68.7% of the participants had no idea about the required investigation. Meanwhile, those who had some information on the required investigation mentioned that liver function tests, kidney function tests and complete blood count are the top priority investigations, followed by lipid profiles and pregnancy test. A previous study conducted by Rao et al.(20) has shown an increase in the level of liver enzymes, total cholesterol and serum triglycerides in 6% of participants, while there was no change in white blood cells count, haemoglobin level and platelet count. More attention should be paid to educate patients who will start isotretinoin therapy, about the importance of measuring lipid profiles, liver function tests and full blood count before starting the treatment and after 1 month of its initiation, repeating these investigations every 3 months(12).

In the present study, the awareness about the importance of pregnancy test before and during isotretinoin was 36.0%, which is low compared to its risk. Isotretinoin is a teratogenic drug as shown in a review conducted by Layton, 2009, which reported that 50% of pregnancies that were exposed to isotretinoin spontaneously abort and about 25% were born with cardiovascular or skeletal deformities (12), which indicates the need for performing pregnancy test before, during and after a course of therapy and providing advice on contraception.

In a study done by Al-Harbi, 2010, 21.1% of students were using oral isotretinoin therapy, and 63.7% of them complained of side effects that interfered with their daily activities (10). In the present study, 37.8% of the participants were using oral isotretinoin, and 32.1% of them developed side effects related to the drug. Differences between both studies might be attributed to a different sample size and the subjects involved, as the study conducted in Qassim region was made on both male and female students, while our study was conducted only among female students.

Concerning the total level of awareness, the majority of the participants (84.7%) in the present study had insufficient knowledge and a poor level of awareness compared to 15.3% who had adequate knowledge and good awareness level, which is lower than that reported in the previous study (10). This difference in the level of awareness about isotretinoin drug might be related to the lack of health education concept among dermatologists in Medina, where the main source of information in the study was doctors. The other possible reason is that health education programs about this commonly used drug were done previously in Qassim region. Therefore, these findings indicate the need for devoting more time to educate patients about the ways to avoid and deal with the side effects of isotretinoin, concentrating on the explanation of common side effects, appropriate methods, and frequency of moisturization, safety rules and precautions during the use of oral isotretinoin therapy.

It should be emphasized that the main limitation of this study was the low level of response among participants and that the collected data were self-re¬ported, with consequent risk of bias and inaccuracy. Furthermore, as it was not a community-based but a cross-sectional study conducted only at the female section of two colleges of Taibah University, This study cannot firmly establish causal relations, and the results may not be generalized to the rest of the university students.

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Conflict of Interests
The authors declare that they have no conflict of interests.

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Appendix A

QUESTIONNAIRE

Awareness of Taibah University female students toward risks and safety of using oral isotretinoin for acne treatment

We are medical students at Taibah University; this questionnaire includes questions that will help us to determine the level of awareness toward oral isotretinoin named as Roaccutane (Roche Pharma AG, Germany) /Accutane (Roche Laboratories, United State) for acne treatment among students at Taibah University. Please help us by filling in this questionnaire; your name will not appear in the research. This study is only for scientific research. Your filling confirms agreement for participation.

I- Socio-demographic information:

- Age: ……. (years)
- College: □Medicine □Nursing
- Marital status: □ Married □ Unmarried
- Study year:

□ First year □Second year □ Third year □ Fourth year □Fifth year

- Residence: □ Urban □ Rural

II- Awareness of oral isotretinoin therapy (named as Roaccutane/Accutane) and the risks and adverse effects related to its use

1. Do you know oral isotretinoin drug (Roaccutane/ Accutane)?

□ Yes
□ No

If yes,

2. What is your source of information?

□ Doctors
□ Pervious patient
□ Friends
□ The family
□ Internet
□ Newspaper
□ Pharmacist
□ Others ……

3. Do you know the risks and side effects of using oral isotretinoin drug?

□ Yes
□ No

If yes,

4. What risks and adverse effects do you know of oral isotretinoin therapy? (You can choose more than one answer):

□ Teratogenicity
□ Dryness
□ Constipation
□ Lipid profile disturbance
□ Hepatic side effects
□ Depression
□ Anaemia
□ Others …….

5. Who are at-risk patient group for using isotretinoin?

□ Pregnant women
□ Breastfeeding women
□ Women with childbearing potential
□ Children
□ Elderly people
□ Adults

III- Awareness of safety issues and precautions for usage of oral isotretinoin therapy.

(You can choose more than one answer):

6. What are the safety issues and precautions for using Roaccutane/Accutane (oral isotretinoin)?

□ Use of contraception among married women during oral isotretinoin therapy
□ Regular specific investigations for follow-up
□ Avoid exposure to sunlight and use of sun protection product while using oral isotretinoin drug
□ Avoid taking other drug/herbal medications without medical counselling
□ Avoid blood donation during oral isotretinoin therapy
□ Avoid laser treatments for a period of 1 year following the end of treatment
□ Contraindicated in patients allergic to peanuts or soya
□ Not to take vitamin supplements containing Vitamin A during oral isotretinoin therapy
□ Others …….

7. What are the investigations that should be done regularly during treatment with isotretinoin?

□ Liver function tests
□ Kidney function tests
□ Lipid profiles
□ Complete blood count (CBC)
□ Pregnancy test

IV- Additional questions to be filled by those who used or are currently using isotretinoin

8. Did you use oral isotretinoin known as Roaccutane/ Accutane before or are you currently using it?

□ Yes
□ No

a. If yes, who prescribed it?

1- Physician ( )
2- Took it by yourself ( )

b. For how long did you use it? ……

9. Did you receive any counselling before you started using oral isotretinoin therapy?

□ Yes
□ No

10. Did you develop any side effects during its use?

□ Yes
□ No

If yes: what is it?.....