

## KNOWLEDGE AND AWARENESS LEVEL ABOUT THE SIDE EFFECTS OF ISOTRETINOIN AMONG SAUDI POPULATION

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### Abstract

**Background:** Isotretinoin is a drug used for the treatment of severe nodular acne that has failed to improve after receiving traditional dermatological therapies. It is classified to the retinoids class of prescribed medications. The effects of this medication might involve dry skin and mucous membranes, deteriorating lipid profile, psychological effect, and induce teratogenic effect. **Objectives:** The purpose of this study is to determine knowledge and awareness of the adverse effects of Isotretinoin (Roaccutane) among Saudi population. **Methods:** This was a study with a cross-sectional design. The targeted population is Saudi population of males and females over the age of 18 who are using an Isotretinoin. **Results:** The sample size were 548 participants. Regarding the participants' knowledge and awareness of side effect of Roaccutane, out of 172 participants who were on Roaccutane treatment, 66.2% were aware of Roaccutane side effects in pregnant women. However, 14.0% remained unaware of these risks. Additionally, 6.0% of participants became pregnant during treatment, indicating poor knowledge and awareness, yet only 11.6% communicated their pregnancy to healthcare providers. Additionally, we have found that participants being informed about Roaccutane side effects has statistically significant relation to gender (p value=0.0001), age (p value=0.021), nationality (p value=0.004) and if participants have had acne in the past (p value=0.0001). It also shows statistically insignificant relation to total family income and if participants have acne now. **Conclusion:** the study highlights a critical gap in knowledge and awareness regarding isotretinoin (Roaccutane) side effects among the Saudi population, particularly in relation to its teratogenic effects. Of the 548 participants surveyed, only 66.2% of those currently undergoing treatment (172) were aware of the risks it poses to pregnant women, with 14.0%

remaining uninformed. Alarming, 6.0% of participants became pregnant during their treatment, underscoring the urgent need for enhanced education and communication regarding isotretinoin's potential side effects. The data also reveal a significant communication deficit, as only 11.6% of those who became pregnant disclosed this information to healthcare providers. Moreover, sociodemographic factors such as gender ( $p=0.0001$ ), age ( $p=0.021$ ), and previous acne history ( $p=0.0001$ ) showed a significant relationship with awareness levels.

**Keywords:** Roaccutane, prevalence, knowledge, acne, isotretinoin.

### Introduction:

Acne vulgaris (AV) is a chronic, multifaceted, cutaneous inflammatory disease of the sebaceous glands, ducts, and hair follicles (better known as the pilosebaceous unite), which usually manifests itself on the face, back, and chest of the patient [1]. AV Therapies range from topical retinoids and antimicrobial agents, which are applied topically, to systemically administered oral agents such as isotretinoin and antibacterial treatment [2]. Isotretinoin, a form of vitamin A derivative, is a manufactured retinol medication marketed as Accutane or Roaccutane and authorized by the (FDA), as the drug of choice to control moderate and severe acne due to its exceptional efficacy in treating such cases [3]. But, despite its capability, isotretinoin has been related to a number of adverse effects, the most common of which are being mucocutaneous in nature, such as retinoid dermatitis, cheilitis, and even conjunctivitis, which are mostly dose-dependent [4]. In addition to those, an aberrant lipid profile and psychological difficulties are usually encountered during the course of this treatment, as well as its teratogenic effect; Therefore, all females of the reproductive age are strongly advised to utilize two or more types of contraception while on this course of medication [5]. The most widespread dermatological condition effecting teenagers is acne vulgaris, which affects more than 80 percent of adolescents [6]. Studies revealed that the teratogenic effect of isotretinoin was linked to a broad range of birth problems, including abnormalities of the neurological system, cardiac, craniofacial [7] A research has been conducted in 2013 to assess the knowledge and awareness of isotretinoin side effects among pharmacy students showed that 87% of students were aware of the common side effects such as dryness of lips, mouth and eyes. However, unlike dryness, the knowledge of the other side effects such as depression and abortion were 37% and 19.8% respectively [8]. Another study assessed knowledge and awareness about the teratogenic effects of oral isotretinoin among women in Saudi Arabia showed that 85% of women were aware of the side effects of isotretinoin. Nevertheless, a significant fraction of 29% took this information from Internet which raises red flags because these sources might be ineligible [9]. Additionally, Alshaalan's study (2022) was the first to assess knowledge of the use of isotretinoin and its side effects among female acne patients of the reproductive age group, found that nearly two-thirds (68.2%) were aware of the teratogenic side effects which was considered an "alarming phenomenon" that shows a low level of awareness. Another interesting finding of the study revealed that less than half of the participants (42%) received instructions related to the importance of contraceptive usage before starting treatment [2]. To assess the awareness level of isotretinoin use among people who live in Saudi Arabia, study is needed because of the series of side effects that can occur due to the incorrect use of isotretinoin [10]. The knowledge gap in the previous studies was limited only to a selected group of female college students or the Jordanian population [10,11]. The aim of this study was to determine the knowledge level among Saudi population about the side effect of using the isotretinoin (Roaccutane) for Acne management.

**Methods**

This is a cross-sectional study was conducted in Saudi Arabia throughout 2023 and 2024. For this study a standardized online questionnaire was distributed among adults' Saudi population of males and females over the age of 18 who are using an Isotretinoin.

**Sample size:**

The sample size was estimated to be at least 38 participants, using the Raosoft calculator with a confidence level of 95% and margin error determined as 5%. The Sample size was appraised by the formula:  $n = P(1-P) * Z_{\alpha/2}^2 / d^2$  with a confidence level of 95%.

n: Calculated sample size

Z: The z-value for the selected level of confidence  $(1 - \alpha) = 1.96$ .

P: An estimated prevalence of knowledge

Q:  $(1 - 0.50) = 50\%$ , i.e., 0.50

D: The maximum acceptable error = 0.05.

So, the calculated minimum sample size was:

$n = (1.96)^2 \times 0.50 \times 0.50 / (0.05)^2 = 384$ .

**Method for data collection, instrument, and score system:**

The study used a questionnaire on aims to determine knowledge and awareness of the adverse effects of Isotretinoin (Roacutane). This questionnaire was developed after reviewing relevant studies conducted in Saudi Arabia. Data was collected through the participants' responses to the questions.

The questionnaire contain 6 questions of socioeconomic background, 2 questions general information about acne, 3 questions about Roacutane usage, 5 questions regarding to Side effect, 8 questions exclusive to married females only.

**Data collection procedure:** This study used quantitative data collected through a previously validated survey via an online questionnaire in English and Arabic. The questions have been changed in an understandable order to reflect the goals of the study. It is composed of 3 sections including demographic data, usage of Roacutane, knowledge and awareness of side effect of Roaccutan.

**Data analysis:** The collected data was tabulated and entered into the Statistical Package for Social Sciences (SPSS) v29. Descriptive analysis was conducted using frequencies, means, standard deviation, and percentages to show participant's demographics and their perceptions towards the knowledge and awareness of isotretinoin side effects. To identify statistical differences in the degree of knowledge and awareness about the side effects of the medication, inferential statistics of chi-square ( $X^2$ ) statistical analysis. The descriptive analysis was provide comprehensive insights into the participants knowledge and awareness level of the side effects of isotretinoin.

**Ethical Considerations:**

The ethical approval was obtained from University of Tabuk, the objective of the study was shortly explain to the study participants. Then, the electronic consent at the beginning of survey was obtained before answering the questionnaire.

**Results:**

Table (1) displays various demographic parameters of the participants with a total number of (548). The mean age of the participants is 27.6 years, with a standard deviation of 9.3, indicating a relatively young population. Most of the participants are female (84.3%), and the overwhelming majority are Saudi nationals (92.7%). The data also reveals the regional distribution of the participants, with the highest representation from the Najran region (22.3%), followed by the Makkah Al-Mukarramah region (17.9%) and the Eastern Region (17.5%). Regarding marital status, most of the participants are single (71.2%), while 25.9% are married, and a small percentage are divorced (2.6%) or widowed (.4%). In terms of educational attainment, most of the participants hold a bachelor's degree (67.9%), with a notable proportion having a high school education (27.7%) and a small percentage holding master's (2.6%) or doctoral (1.1%) degrees. The data on total family income shows a relatively diverse distribution, with the highest proportion (36.5%) earning more than 15,000 Saudi Riyals per month. The data also provides insights into the participants' self-reported acne status, with 39.1% experiencing acne during some days of the month, 23.0% always having acne, and 38.0% reporting no acne. This information could be valuable in understanding the prevalence and patterns of acne among the study population.

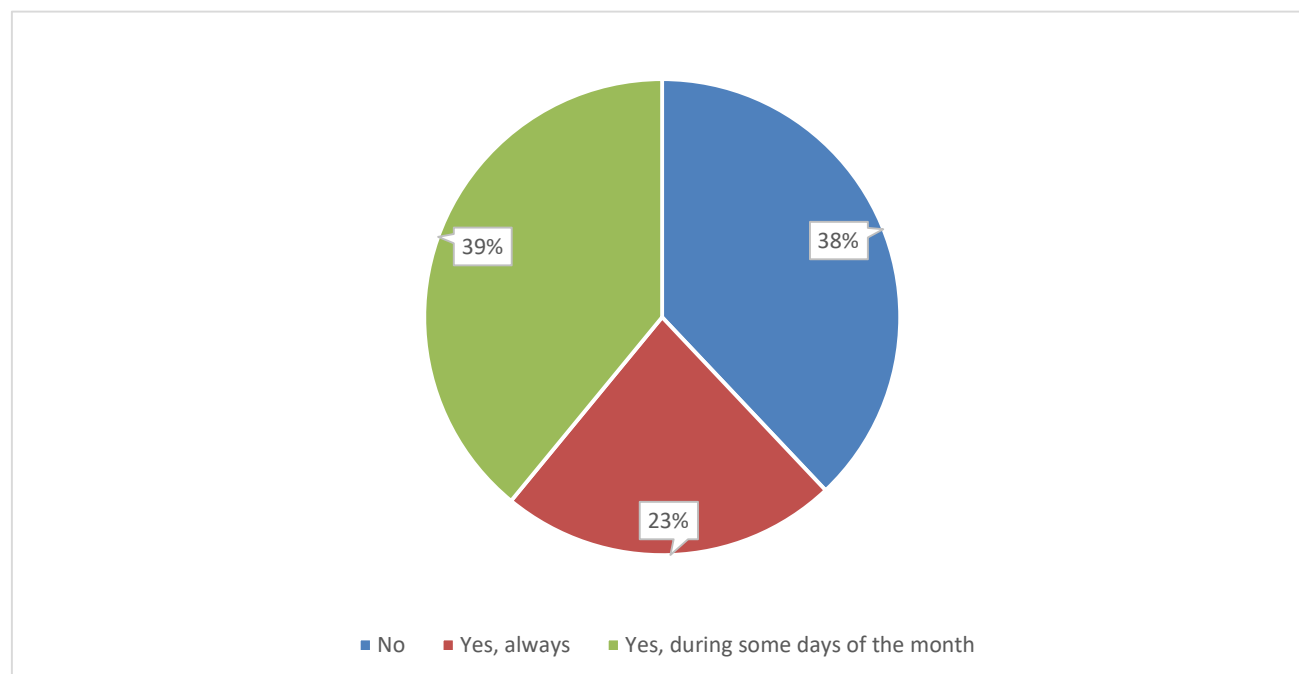
**Table (1): Sociodemographic characteristics of participants (n=548)**

<b>Parameter</b>		<b>No.</b>	<b>Percent (%)</b>
<b>Age</b> (Mean: 27.6, STD: 9.3)	21 years or less	167	30.5
	21 to 24	133	24.3
	24 to 35	144	26.3
	more than 35 years	104	19.0
<b>Gender</b>	Female	462	84.3
	Male	86	15.7
<b>Nationality</b>	Non-Saudi	40	7.3
	Saudi	508	92.7
<b>Region of residence</b>	Asir Region	10	1.8
	Jazan region	2	.4
	Makkah Al-Mukarramah region	98	17.9
	Medina region	50	9.1
	Najran region	122	22.3
	Northern border region	2	.4
	Riyadh region	74	13.5
	Tabuk region	94	17.2
	The Eastern Region	96	17.5
<b>Marital status</b>	Single	390	71.2
	Married	142	25.9
	Divorced	14	2.6
	Widowed	2	.4
<b>Education level</b>	Secondary school graduate	4	.7
	High school graduate	152	27.7
	Bachelor's degree	372	67.9

	Master's degree	14	2.6
	Ph.D. degree	6	1.1
<b>Total family income</b>	Less than 5000	106	19.3
	10000-5000	118	21.5
	15000-11000	124	22.6
	More than 15000	200	36.5
<b>Do you have acne now?</b>	No	208	38.0
	Yes, always	126	23.0
	Yes, during some days of the month	214	39.1

As shown in figure 1, The data presented in the figure provides valuable insights into the prevalence and patterns of acne among the surveyed individuals. The largest proportion, 214 respondents, indicated that they experience acne during certain days of the month, suggesting a potential hormonal or cyclical component to their condition. This group may benefit from targeted interventions and monitoring to better manage their acne flare-ups. Interestingly, a sizable number of 208 respondents reported not having acne at all, which could imply a relatively healthy or resilient skin condition for this segment of the sample. In contrast, 126 individuals stated that they consistently struggle with acne, potentially requiring more comprehensive medical or dermatological care to address the underlying causes and find effective long-term solutions.

**Figure (1): Illustrates whether participants have acne now.**



As illustrated in table (2), The data provided in the table offers valuable insights into the usage patterns and side effects associated with the drug Roaccutane (also known as Isotretinoin or Accutane). The information gathered from a sample of 548 individuals highlights the prevalence of acne as a prevalent skin condition, with 79.6% of respondents reporting a history of acne. The data also reveals that the

majority of Roaccutane users (65.7%) received the prescription from a physician, indicating the drug's clinical significance in addressing acne-related issues. Regarding the form of treatment, the data shows that the majority of respondents (77.7%) opted for the pill form of Roaccutane, while a smaller percentage utilized topical creams (18.6%) and gels (3.6%). The duration of use is also noteworthy, with 53.6% of respondents reporting a usage period of less than 6 months, and 39.1% using the drug for 6 months to a year. The data on side effects provides a comprehensive understanding of the potential challenges associated with Roaccutane use. The most reported side effects include musculoskeletal pain (22.2%), increased cholesterol/triglycerides (11.6%), and hair loss (9.8%). Interestingly, 32.8% of respondents reported not experiencing any side effects, while a sizable proportion (35.7%) experienced side effects other than those listed. The information regarding the severity of dryness experienced by users is also noteworthy, with 41.6% reporting moderate dryness and 28.1% experiencing severe dryness. Additionally, 12% of respondents reported being diagnosed with depression or suicidal thoughts while using Roaccutane, highlighting the importance of closely monitoring the mental health of patients during treatment.

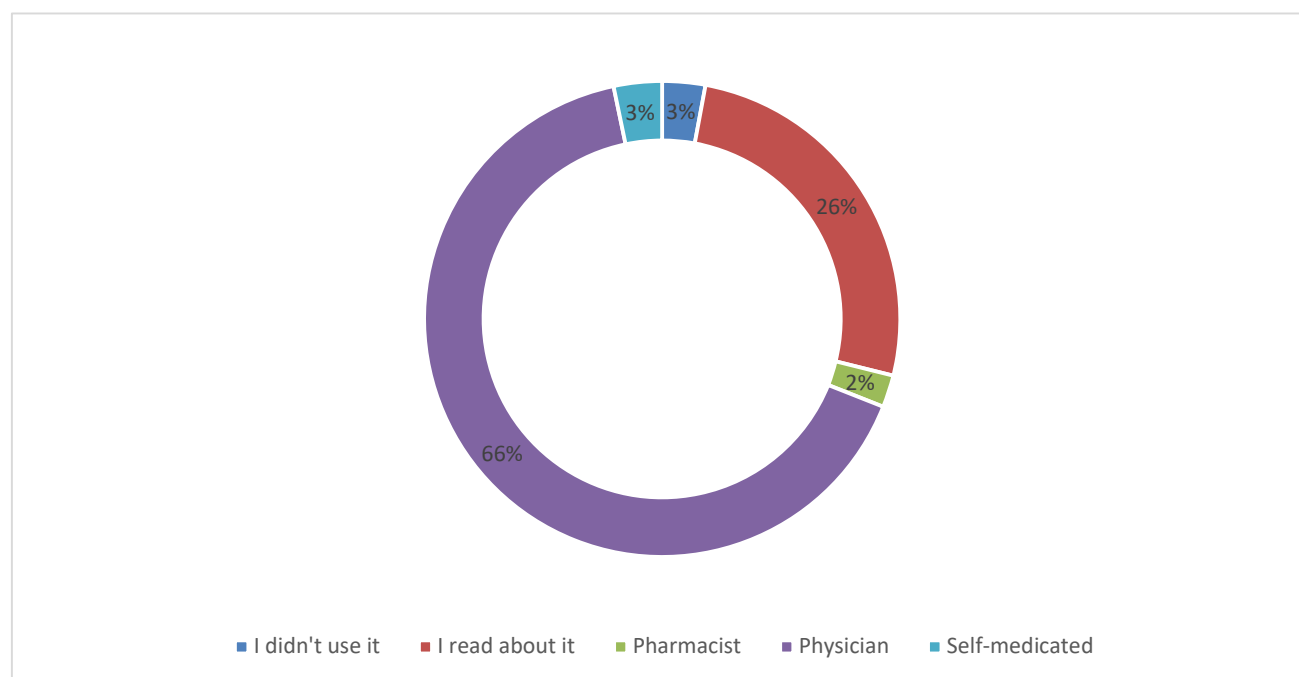
**Table (2): Parameters related to the usage of Roaccutane (n=548).**

<b>Parameter</b>		<b>No.</b>	<b>Percent (%)</b>
<b>Have you had acne in the past?</b>	No	112	20.4
	Yes	436	79.6
<b>If you have used Roaccutane, who prescribed it for you?</b>	I didn't use it	16	2.9
	I read about it	142	25.9
	Pharmacist	12	2.2
	Physician	360	65.7
	Self-medicated	18	3.3
<b>What form of treatment is used?</b>	cream	102	18.6
	gel	20	3.6
	pill	426	77.7
<b>For how long did you use Roaccutane?</b>	I didn't use it	15	2.7
	Less than 6 months	294	53.6
	6months to a year	214	39.1
	More than one year	25	4.6
<b>Have you been informed about the side effects of Roaccutane before using it or during the treatment period?</b>	No	76	13.9
	Yes	406	74.1
	I don't know	66	12.0
<b>If you had any side effects, please mention it. *</b>	Cholesterol / triglycerides increase	64	11.6
	Hair loss	54	9.8
	Musculoskeletal pain	122	22.2
	Eye dryness	4	0.7
	Depression	2	0.4
	I didn't use it	14	2.5
	Other	196	35.7
	I didn't have any side effects	180	32.8

<b><i>Describe your dryness while you're using Roaccutane.</i></b>	I didn't experience dryness	80	14.6
	Light	56	10.2
	Moderate	228	41.6
	Normal	30	5.5
	sever	154	28.1
<b><i>Have you been diagnosed with Depression / Suicide thoughts, while you're using Roaccutane?</i></b>	No	482	88.0
	Yes	66	12.0
<b><i>Choose all the side effects of Roaccutane that you know? *</i></b>	Depression	342	62.4
	Dryness	470	85.7
	Fetal malformation	276	50.3
	Kidney failure	192	35.0
	Miscarriage	154	28.1
	Sleep disorders	142	25.9
	Increase blood glucose level	84	15.3
	Increased blood cholesterol	202	36.8
	Liver problems	292	53.2

\*Results may overlap

As shown in figure (2), Analyzing the data presented in the figure, it becomes evident that most individuals who have utilized Roaccutane (also known as Isotretinoin) did so under the guidance and prescription of a physician. This is a significant finding, as Roaccutane is a potent medication with a range of potential side effects, and its use should be carefully monitored and supervised by a qualified medical professional. The comparatively smaller numbers of individuals who either read about Roaccutane or self-medicated further highlight the importance of seeking professional medical advice before embarking on any treatment regimen involving this medication. It is encouraging to see that the role of pharmacists in the prescription and administration of Roaccutane is also recognized, as they can play a vital role in ensuring the safe and effective use of this treatment.

**Figure (2): Illustrates who prescribed Roaccutane for the participants.**

In table (3), The presented data provides valuable insights into the knowledge and awareness of participants regarding the potential side effects of Roaccutane, a medication commonly used to treat severe acne. The findings highlight several critical aspects that warrant further discussion and consideration. Firstly, the data reveals a significant demographic disparity, with the majority of participants being single females (58.8%), followed by married females (26.3%), single males (13.9%), and married males (1.1%). This gender-skewed distribution suggests that the awareness and utilization of Roaccutane may be more prevalent among the female population, underscoring the importance of targeted educational efforts and access to information for all individuals who may potentially use this medication. Notably, among the 172 participants who had used Roaccutane, a considerable proportion (67.4%) did not use the medication after marriage, indicating a possible awareness or concern regarding the potential impact on pregnancy and fetal development. This is further supported by the finding that 66.2% of the participants were aware of the side effects of Roaccutane on pregnant women. However, the data also reveals that a significant number of participants (14.0%) were unaware of these risks, highlighting the need for more comprehensive patient education and counseling by healthcare professionals. Furthermore, the survey results suggest that not all participants who used Roaccutane were adequately advised or prescribed contraceptive methods during the treatment period. Only 27.9% of the respondents reported being advised to use contraceptives, while a significant proportion (41.9%) did not use Roaccutane at all or were single females. This highlights a potential gap in the standard of care and the need for healthcare providers to prioritize the importance of contraception counseling and management, particularly for individuals of reproductive age. The data also reveals that a small percentage of participants (6.0%) became pregnant during or around the Roaccutane treatment period, which is concerning given the well-established teratogenic effects of the medication. Alarming, only 11.6% of these participants reported informing their healthcare providers about the pregnancy, suggesting a lack of open communication and potential missed opportunities for appropriate medical



intervention and management.

**Table (3): participants' knowledge and awareness of side effect of Roaccutane (n=548).**

<b>Parameter</b>		<b>No.</b>	<b>Percent (%)</b>
<b>Single or married (male or female)</b>	Married female	144	26.3
	Married male	6	1.1
	Single female	322	58.8
	Single male	76	13.9
<b>Did you use Roaccutane after marriage? (n=172)</b>	I'm single female	22	12.8
	No	116	67.4
	Yes	34	19.8
<b>Did you know about side effect of Roaccutane on pregnant women? (n=172)</b>	I don't use it	34	19.8
	No	24	14.0
	Yes	114	66.2
<b>Have you been advised to use contraceptives during Roaccutane treatment period? (n=172)</b>	I don't use it	72	41.9
	I'm single female	20	11.6
	No	32	18.6
	Yes	48	27.9
<b>If yes, how many contraceptive methods have been prescribed to you? (n=172)</b>	I didn't use it	96	55.8
	I'm single female	28	16.3
	More than 2 methods	2	1.2
	No prescription has been made to me	12	7.0
	One method	22	12.8
	Two method	12	7.0
<b>Have you been informed about fetus teratogenicity if you become pregnant during Roaccutane treatment? (n=172)</b>	I didn't use it	84	48.8
	I'm single female	26	15.1
	No	14	8.1
	Yes	48	27.9
<b>What's your knowledge degree about teratogenic effect of Roaccutane on pregnant women? (n=172)</b>	High	72	41.9
	Low	18	10.4
	Moderate	22	12.8
	None	60	34.9
<b>Did you get pregnant (1 month before using OR during Roaccutane treatment OR during the first month after discontinuation of treatment)? (n=172)</b>	I didn't use it when I'm married	100	58.1
	I'm single female	26	15.1
	No	34	19.8
	yes, during the treatment	6	3.5
	Yes, 1 month before the treatment	4	2.3
	Yes, during the first month after discontinuation of treatment	2	1.2

<b><i>If you became pregnant (1 month before using OR during Roaccutane treatment OR during the first month after discontinuation of treatment), did you inform your doctor? (n=172)</i></b>	I didn't get pregnant during this period	16	9.3
	I didn't use it when I'm married	98	57.0
	I'm single female	26	15.1
	No	12	7.0
	Yes	20	11.6

Table (4) shows that the fact that participants being informed about Roaccutane side effects has statistically significant relation to gender (p value=0.0001), age (p value=0.021), nationality (p value=0.004) and if participants have had acne in the past (p value=0.0001). It also shows statistically insignificant relation to total family income and if participants have acne now.

**Table (4): Relation between if participants had been informed about Roaccutane side effects and sociodemographic characteristics.**

<b><i>Parameters</i></b>		<b><i>Been informed about side effects of Roaccutane</i></b>		<b><i>Total (N=548)</i></b>	<b><i>P value*</i></b>
		<b><i>No or not known</i></b>	<b><i>Yes</i></b>		
<b><i>Gender</i></b>	Female	104	358	462	0.0001
		73.2%	88.2%	84.3%	
	Male	38	48	86	
		26.8%	11.8%	15.7%	
<b><i>Age</i></b>	21 years or less	48	119	167	0.021
		33.8%	29.3%	30.5%	
	21 to 24	36	97	133	
		25.4%	23.9%	24.3%	
	24 to 35	24	120	144	
		16.9%	29.6%	26.3%	
	more than 35 years	34	70	104	
		23.9%	17.2%	19.0%	
<b><i>Nationality</i></b>	Non-Saudi	18	22	40	0.004
		12.7%	5.4%	7.3%	
	Saudi	124	384	508	
		87.3%	94.6%	92.7%	
<b><i>Region of residence</i></b>	Asir Region	6	4	10	N/A
		4.2%	1.0%	1.8%	
	Jazan region	2	0	2	
		1.4%	0.0%	0.4%	
	Makkah Al-Mukarramah region	22	76	98	
		15.5%	18.7%	17.9%	
	Medina region	14	36	50	
		9.9%	8.9%	9.1%	

	Najran region	30	92	122	
		21.1%	22.7%	22.3%	
	Northern border region	0	2	2	
		0.0%	0.5%	0.4%	
	Riyadh region	14	60	74	
		9.9%	14.8%	13.5%	
	Tabuk region	22	72	94	
		15.5%	17.7%	17.2%	
<b>Marital status</b>	Single	32	64	96	N/A
		22.5%	15.8%	17.5%	
	Married	96	294	390	
		67.6%	72.4%	71.2%	
	Divorced	38	104	142	
		26.8%	25.6%	25.9%	
	Widow	8	6	14	
		5.6%	1.5%	2.6%	
<b>Education level</b>	Secondary school graduate	0	2	2	N/A
		0.0%	0.5%	0.4%	
	High school graduate	2	2	4	
		1.4%	0.5%	0.7%	
	Bachelor	62	90	152	
		43.7%	22.2%	27.7%	
	Master's degree	76	296	372	
		53.5%	72.9%	67.9%	
<b>Total family income</b>	Master's degree	2	12	14	0.765
		1.4%	3.0%	2.6%	
	Ph.D. degree	0	6	6	
		0.0%	1.5%	1.1%	
	Less than 5000	26	80	106	
		18.3%	19.7%	19.3%	
	5000 to 10000	34	84	118	
		23.9%	20.7%	21.5%	
<b>Do you have acne now?</b>	11000 to 15000	34	90	124	0.522
		23.9%	22.2%	22.6%	
	More than 15000	48	152	200	
		33.8%	37.4%	36.5%	
	No	56	152	208	
		39.4%	37.4%	38.0%	
	Yes, always	36	90	126	
		25.4%	22.2%	23.0%	
<b>Have you had acne in the past?</b>	Yes, During some days of the month	50	164	214	0.0001
		35.2%	40.4%	39.1%	
	No	52	60	112	
		36.6%	14.8%	20.4%	

	Yes	90	346	436	
		63.4%	85.2%	79.6%	

*\*P value was considered significant if  $\leq 0.05$ .*

### Discussion:

Acne vulgaris is a common skin condition affecting 9.4% of the global population. It has a high incidence among young adults and adolescents. Oral isotretinoin is considered a first-line treatment for severe forms of acne vulgaris [12]. Isotretinoin has proven to be an effective treatment for acne vulgaris with an overall safety profile. Despite the high efficacy of isotretinoin in treating acne, it displays numerous significant side effects, with dry skin and lips being the most commonly reported, affecting 100% of patients [13]. The effect of oral isotretinoin on serum lipids, namely a significant elevation in blood triglyceride and cholesterol levels, was also reported. Additionally, in some case reports, isotretinoin was found to cause pancreatitis secondary to hypertriglyceridemia [14]. It also has a risk effect on bone health, causing a reduction in bone mineral density [15]. Although isotretinoin therapy may have significant side effects, multiple studies have shown a lack of awareness of these side effects. A study conducted in the western region of Saudi Arabia revealed that 15%-50% of patients who used oral isotretinoin for acne lacked knowledge about the side effects of isotretinoin treatment [16]. Thus, we aimed in this study to measure the knowledge and awareness level among Saudi Arabia population about the side effect of using the isotretinoin (Roacutane) for Acne management

Regarding the participants' knowledge and awareness of side effect of Roacutane, out of 172 participants who were on Roacutane treatment, 66.2% were aware of Roacutane side effects in pregnant women. However, 14.0% remained unaware of these risks. Additionally, 6.0% of participants became pregnant during treatment, indicating poor knowledge and awareness, yet only 11.6% communicated their pregnancy to healthcare providers. In comparison to previous studies, our findings were paralleling the 68.2% awareness of teratogenicity reported among female patients in KSA [17]. Notably, our study indicates a significant gap in communication, with only 11.6% disclosing pregnancies to healthcare providers, reflecting a broader trend of inadequate knowledge and awareness reported in the KSA context, where nearly 60% of participants fell into a low knowledge category about isotretinoin's risks. Consistent with our findings, Alshaalan [18] found that 60% of female acne patients had a low level of knowledge. This corroborates with the study of Shajeri et al., stating that the general population's knowledge was poor, with a mean knowledge score of 2.1 (SD = 2.2) out of 9 points [19]. On the other hand, a study in Al Madina, Saudi Arabia, showed that 45.6% of participants were not notified about the side effects of the drug. Additionally, the study showed that the major sources of information on isotretinoin were friends (45.2%) and social media (41.8%) [20]. On the contrary, a study conducted among the Al-Madinah population reported satisfactory knowledge about isotretinoin side effects, with 70% having heard of isotretinoin, and over 60% knowing of its side effects, which were consistent with the study done in the Qassim region [21].

Regarding another aspect of side effects, a recently published study from Jordan by Jarab AS et al. in 2022 reported a higher proportion of participants aware of not donating blood while on isotretinoin [22]. Another study conducted by Imam SA et al. in 2021 showed that almost half (50.5%) of their study participants did not know that they should not donate blood during the treatment [23].

Regarding the relation between if participants had been informed about Roacutane side effects and sociodemographic characteristics, we have found that participants being informed about Roacutane side effects has statistically significant relation to gender (p value=0.0001), age (p value=0.021), nationality (p value=0.004) and if participants have had acne in the past (p value=0.0001). It also shows statistically insignificant relation to total family income and if participants have acne now. However, In

Jeddah [24], a study documented an association between gender and knowledge about medication side effects along with safety precautions that pregnant women should be aware of during medication use, wherein females exhibited better knowledge and awareness of the necessary measures. This is comparable with the study of Jarab et al. [25], who reported female gender and isotretinoin use for more than six months to be significantly associated with a higher knowledge score. However, in the study by Molla et al. [26], the age group showed a significant relationship with knowledge about Roaccutane.

**Conclusion:**

In conclusion, this study underscores a significant knowledge gap among the Saudi population regarding the side effects of isotretinoin (Roaccutane) used for acne management. While a majority of participants recognized the drug's teratogenic risks, a notable proportion remained unaware of its potential complications, including serious mucocutaneous effects and implications for pregnancy. The data reveal an urgent need for improved educational initiatives targeting both patients and healthcare providers to enhance awareness of isotretinoin's risks, especially given the alarming statistic of participants not disclosing pregnancies during treatment. Furthermore, the study highlights the varying levels of awareness across demographic groups, emphasizing the importance of tailored educational strategies to ensure that critical safety information reaches all patients, thereby fostering safer treatment outcomes for those affected by acne vulgaris.

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**Ethical approval:**

An informed consent was obtained from each participant after explaining the study in full and clarifying that participation is voluntary. Data collected were securely saved and used for research purposes only.

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**Conflict of interests:**

The authors declare no conflict of interest.

**Informed consent:**

Written informed consent was acquired from each individual study participant.

**Data and materials availability:**

All data associated with this study are present in the paper.

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