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KNOWLEDGE AND AWARENESS OF ORAL ISOTRETINOIN'S OCULAR SIDE EFFECTS IN SAUDI POPULATION

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Abstract

Background: Isotretinoin is frequently used to treat severe acne, although its usage is constrained by systemic, mucocutaneous, and ocular adverse effects. It is frequently regarded as the most effective kind of treatment in such circumstances. The purpose of this study was to assess the population's level of awareness and understanding about the ocular side effects of oral isotretinoin.
Methodology: This is a questionnaire-based observational study that was conducted in Saudi Arabia from Aug 2023 – September 2024. The study's population consisted of Saudi Arabia population in both gender from the age 18 to 60. participants were recruited from people receiving questionnaire.
Results: As regard knowledge score about isotretinoin side effects, 42.6% of the sample, demonstrated a high level of knowledge about this medication. However, a sizable proportion of the participants, approximately 33.6%, exhibited a moderate level of knowledge, while 23.9% were classified as having a low level of understanding. Regarding the awareness score (67.8%) exhibits poor awareness. However, 10% exhibits moderate awareness and 22.1% exhibited high awareness. Moreover, (64.4%) were aware that oral isotretinoin can cause dryness of the eyes. Additionally, smaller percentage of participants were aware of other potential ocular side effects, such as itchiness (50.2%), burning sensation (45.7%), blurred vision (33.2%), and eyelid inflammatory conditions (34.9%).
Conclusion: While a significant portion of the participants demonstrated a high level of knowledge about the medication itself, there was a concerning lack of awareness about specific ocular side effects, with a majority exhibiting poor awareness overall. The most commonly recognized ocular side effect was dryness of the eyes, while awareness of other potential side effects such as itchiness, burning sensation, and blurred vision varied.

Keywords: oral isotretinoin, ocular side effects, Saudi Arabia, Acne.

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Introduction:

Acne vulgaris is a common skin condition that affects the pilosebaceous follicles [1]. It is most common in adolescents and young adults but can occur at any age [2]. The condition is characterized by pimples, blackheads, and whiteheads [3]. In moderate-to-severe cases, a medication called Roaccutane can be used as a first-line treatment [4]. One of the active forms of vitamin A, isotretinoin (13-cis-retinoic acid), is mostly used to treat severe skin problems like acne [5]. Acne is the eighth most common disease in the world, affecting 9.4% of the global population [6]. Oral isotretinoin has been proven to be a substantial pharmacological advance in the treatment of severe and persistent cases of acne since it was initially licensed by the US Food and Drug Administration (FDA) in 1982 for the treatment of severe acne [7].

Isotretinoin-related adverse effects are frequent, with ocular symptoms being one of them, despite having an adequate safety profile [8].

In 2020, an observational study conducted on Al-Madinah residents to measure the knowledge regarding isotretinoin use, found that 61.6 percent of the respondents were aware of the possibly harmful adverse effects of isotretinoin [9]. An article from 2022 addressing the awareness of isotretinoin use and its adverse reaction amongst Saudi female user, stated that the sum of individuals with less awareness represented over sixty percent of the studied population [10]. Another observational study was carried out in Saudi Arabia to assess dermatologists' awareness of the potential adverse effects of isotretinoin on the eyes, determined that 97.3 percent of the dermatologists confirmed their awareness of ocular adverse effects [11].

Following a similar study done in 2021 on dermatologists in Egypt, almost all the dermatologists who participated regularly supplied lubricant medication for their patients, and 36.9 percent of the dermatologists did pre-isotretinoin prescription assessments in case of any previous eye surgery for their patient [12].The dermatological condition most frequently treated is acne vulgaris. In Saudi Arabia, it accounts for one-fifth of all visits to dermatology clinics. Additionally, it can affect up to 80% of adolescents, and women are more likely than men to seek medical advice [13]. Isotretinoin has been used extensively to successfully treat severe nodulo-cystic acne .Numerous studies, including the most recent one by Brzezinski, estimate the incidence of isotretinoin's ocular side effects to be around 8.96% [14]. This study aims to assess the level of knowledge and awareness of ocular side effects of oral isotretinoin among the population of Saudi Arabia.

Materials and Methods:

Study design:

This is a questionnaire-based observational study that was conducted in Saudi Arabia from Aug 2023-September 2024.The study's population consisted of Saudi Arabia population in both gender from the age 18 to 60. participants were recruited from people receiving questionnaire.

Inclusion and Exclusion criteria:

The participants in this study were over the age of 18, regardless of gender. Any participant who was under the age of 18 was excluded.

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Sample size:

The sample size for this study was determined minimally to be 377 individuals using the formula provided by Raosoft, Inc. In the calculation, means and standard deviation were considered, along with a standard deviation value of 1.96 for a 95% confidence interval and a maximum acceptable marginal error of 0.05. Thus, the minimum required sample size for this study was 377 participants.

Method for data collection and instrument (*Data collection Technique and tools)*:

The collection of data was conducted by obtaining the participants' responses to the provided questions. The first section of the questionnaire included demographic features such as age, gender, level of education, and occupation (medical field or others). The second section was testing the Saudi Arabian citizens and residents' knowledge about oral isotretinoin ocular side effects. While the third section was containing question about the Saudi Arabian citizens and residents' awareness. Data collectors was collect the information's using an online survey platform (google form) .
In this study, the questionnaire was used from the studies done by Anan Jarab [4], Azizah Malebari [6], Razan AlMasoudi [8], Thuraya Albadr [13], Olivia lamberg [15], Tongabay Cumurcu [17], Fraunfelder [21].

Scoring system:

Part 1: knowledge level regarding oral Isotretinoin ocular side effects 13
There were nine questions in this part and the participants were asked regarding their knowledge of isotretinoin ocular side effects. Questions number 8, 10 and 11 have no score. Question number 12 has 8 correct answers. The other questions have only one correct answer. A correct answer was given 1 score, while a wrong answer was given 0 score. The original Bloom's cut-off points, 80.0%-100.0%, 60.0%-79.0%, and ≤59.0% have been adapted from KAP study conducted toward compliance with abattoir laws among the abattoir workers in Malaysia {Formatting Citation}(15). They have been used to classify KAP into three levels. The scores for knowledge varied from 1 to 13 points and have been labeled into three stages as follows: 1. high level: 10–13 scores; 2. moderate level: 9 scores; and 3. low level: 0–8 score.

Part 2: Awareness level regarding oral Isotretinoin ocular side effects
There were 9 questions on this part and the participants have been asked regarding their awareness level of oral Isotretinoin ocular side effects. Every question had three choices. A correct answer was given 1 score, whereas a zero score was given for an incorrect answer. The original Bloom's cut-off points, 80.0%–100.0%, 60.0%–79.0%, and 59.0%, have been adapted from KAP study conducted toward compliance with abattoir laws among the abattoir workers in Malaysia [18]. They have been used to classify KAP into three levels. The scores for awareness varied from 1 to 9 points and have been labeled into three stages as follows: 1. high level: 7–9 scores; 2. moderate degree: 6 scores; and 3. low level: 0–5 score.

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Analyzes and entry method:

Data was entered on the computer using the "Microsoft Office Excel Software" program (2016) for windows. Data was then transferred to the Statistical Package of Social Science Software (SPSS) program, version 25 (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) to be statistically analyzed.

Results:

Table (1) displays various demographic parameters of a group of people with a total number of (578). The provided data offers valuable insights into the sociodemographic characteristics of the study participants, shedding light on the diversity and composition of the sample. The mean age of 29.2 years, with a standard deviation of 10.8, suggests a relatively young population, with the majority (52.9%) falling within the 21 to 40 age range. The gender distribution shows a predominance of female participants, comprising 79.6% of the sample, which could be reflective of the specific healthcare-related context or the general demographics of the study population. The educational background of the participants is notably diverse, with the majority (72.7%) holding bachelor's degrees, while a small percentage (4.2%) have attained postgraduate qualifications. This suggests a well-educated sample, which could potentially contribute to the reliability and validity of the findings. The marital status data reveals that the majority (61.9%) of participants are single, while 35.6% are married, providing valuable information about the relationship dynamics and social support networks within the study group. The occupational distribution shows that 32.5% of the participants are healthcare professionals, while the remaining 67.5% are engaged in various other professions. This distribution is important to consider when interpreting the study results, as the healthcare professionals may have unique perspectives or experiences that could influence the outcomes. The geographical residence data indicates a widespread representation, with the majority (45%) residing in the eastern region, followed by the southern (36%), central (10.4%), western (6.2%), and northern (2.4%) regions. Finally, the data on participants' history of oral isotretinoin (Roaccutane) usage reveals that the majority (74%) have not taken this medication, while 26% have. This information is crucial for understanding the potential impact of prior exposure to this drug on the study outcomes and the generalizability of the findings to the broader population. In summary, the provided sociodemographic data offers a comprehensive overview of the study participants, highlighting their age, gender, educational attainment, marital status, occupation, geographical residence, and experience with oral isotretinoin. This information is essential for contextualizing the study results, assessing the representativeness of the sample, and identifying potential confounding factors that may influence the interpretation of the findings.

Table (1): Sociodemographic characteristics of participants (n=578)

Parameter		***No.***	***Percent (%)***
Age (Mean: 29.2, STD:10.8)	21 or less	162	28.0
	21 to 24	144	24.9
	24 to 40	162	28.0
	more than 40	110	19.0
Gender	Female	460	79.6
	Male	118	20.4
Education level	Middle school	4	.7

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	High school	84	14.5
	Diploma	46	8.0
	Bachelor's degree	420	72.7
	Postgraduate	24	4.2
Marital status	Single	358	61.9
	Married	206	35.6
	Divorced	12	2.1
	Widowed	2	.3
Occupation	Healthcare professional	188	32.5
	Others	390	67.5
Residence	Northern region	14	2.4
	Southern region	208	36.0
	Central region	60	10.4
	Eastern region	260	45.0
	Western region	36	6.2
Have you ever taken oral isotretinoin (Roaccutane)?	No	428	74.0
	Yes	150	26.0

As shown in figure 1, it is evident that a significant majority of respondents, approximately 74%, have not taken oral isotretinoin (Roaccutane) as a treatment option. This suggests that while Roaccutane may be a viable and effective solution for some individuals struggling with acne, a substantial portion of the population has not resorted to this medication. The relative disparity between the number of respondents who have and have not taken Roaccutane highlights the need for a comprehensive understanding of the potential benefits and risks associated with this treatment, as well as the availability of alternative acne management strategies that may be more suitable for certain individuals. Further exploration of the factors influencing the decision to utilize or refrain from Roaccutane, such as individual medical history, concerns about side effects, or access to healthcare resources, could provide valuable insights into the complexities surrounding acne treatment and the overall management of this common dermatological condition.

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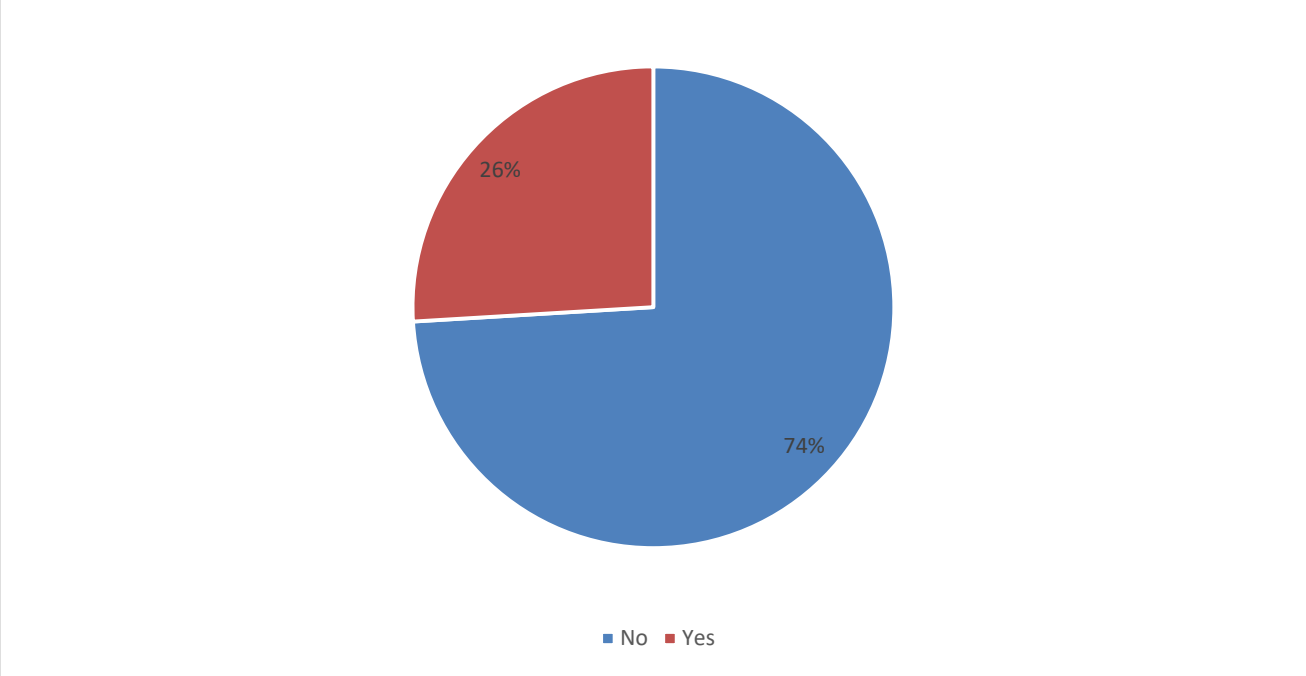
Figure (1): Illustrates whether participants have taken isotretinoin before.



As illustrated in table (2), The provided data presents valuable insights into the knowledge and awareness levels of patients regarding the use of isotretinoin, a drug primarily utilized for the treatment of severe acne. The findings suggest that most of the respondents (66.4%) are aware of the drug, with a significant proportion (83.7%) understanding that it is primarily used to treat severe acne. However, a notable percentage (36.3%) of the participants were not informed about the potential side effects of oral isotretinoin, highlighting the need for improved patient education and communication by healthcare professionals. Interestingly, the data reveals the various sources from which patients received information about the side effects of the medication, with doctors being the primary source (34.6%), followed by family/friends (18.7%) and social media (17.3%). This underscores the importance of healthcare providers taking a proactive role in educating their patients about the risks and benefits associated with isotretinoin use. Furthermore, the data delves into the respondents' understanding of the ocular side effects of isotretinoin, with a significant proportion (64.0%) acknowledging that these side effects are not rare, and half (50.9%) recognizing that high doses of the drug can increase the occurrence of ocular symptoms. However, the mixed responses regarding the reversibility of these side effects upon discontinuation of the medication suggest a need for clearer communication and patient education on this topic. Overall, the data provides a comprehensive overview of the knowledge and awareness levels of patients regarding isotretinoin, which can inform healthcare providers and policymakers in developing more effective strategies for patient education and counseling, ultimately enhancing the safe and responsible use of this medication.

Table (2): Parameters related to knowledge level about isotretinoin (n=578).

Parameter		***No.***	***Percent (%)***
Are you aware of the drug isotretinoin (Roaccutane)?	Yes	384	66.4
	No	102	17.6
	I'm not sure	92	15.9

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Isotretinoin (Roaccutane) is primarily used to treat which condition?	Allergies	78	13.5
	Severe acne	484	83.7
	Diabetes	4	.7
	Hypertension	12	2.1
Were you informed about the side effects of oral Isotretinoin (Roaccutane)?	No	210	36.3
	Yes	368	63.7
Who informed you about the side effects of oral Isotretinoin (Roaccutane)?	Doctor	200	34.6
	Pharmacist	16	2.8
	Family/Friends	108	18.7
	Social media	100	17.3
	Nobody informed me	128	22.1
	Others	26	4.5
Ocular side effects of oral isotretinoin are rare (Roaccutane)?	Yes	180	31.1
	No	370	64.0
	I don't know	28	4.8
High doses of oral Isotretinoin (Roaccutane) can increase the occurrence of ocular symptoms.	Yes	294	50.9
	No	266	46.0
	I don't know	18	3.1
Ocular side effects of oral isotretinoin (Roaccutane) are usually reversible once the medication is discontinued.	Yes	258	44.6
	No	290	50.2
	I don't know	30	5.2
Isotretinoin should be given with plenty of water to avoid dryness.	Yes	446	77.2
	No	112	19.4
	I don't know	20	3.5

In analysing figure (2), it is evident that the topic at hand is related to the awareness of the potential side effects associated with the oral medication Isotretinoin, commonly known by the brand name Roaccutane. The data presented suggests that a significant portion of the surveyed population, approximately 63%, indicated that they were informed about the potential side effects of this medication, while the remaining 37% reported a lack of such awareness. This finding is of particular importance, as Isotretinoin is a potent medication used to treat severe acne conditions, but it is also known to carry a range of potential side effects that can have serious implications for the patient's health and well-being. These side effects can include, but are not limited to, increased risk of depression, liver damage, and birth defects in pregnant individuals. Consequently, it is crucial that healthcare providers and regulatory authorities ensure that patients are thoroughly informed about these risks prior to initiating treatment, enabling them to make informed decisions and actively participate in the management of their condition. The data presented in the figure underscores the need for more robust educational campaigns and improved patient-provider communication to enhance the level of awareness and understanding surrounding the use of Isotretinoin. By empowering patients with comprehensive information, healthcare professionals can help patients navigate the treatment journey with a better understanding of the potential risks and benefits, ultimately leading to improved patient outcomes and overall quality of life.

Figure (2): Illustrates whether participants were informed about the side effects of isotretinoin.

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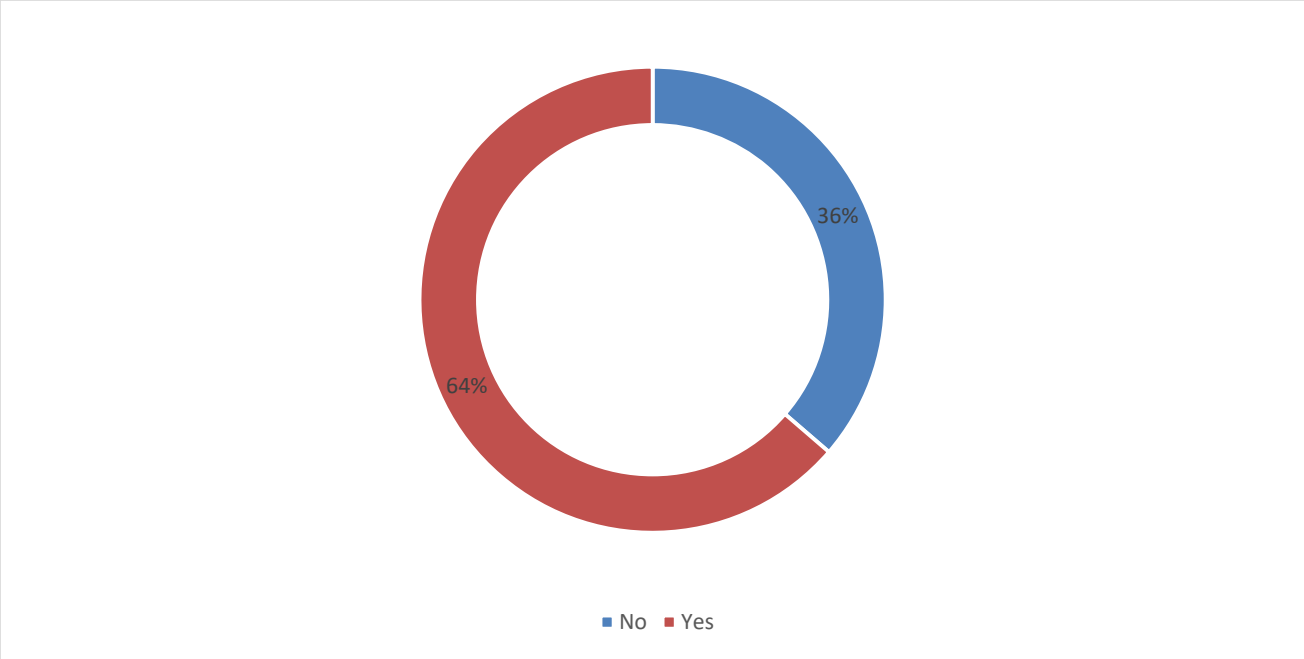

Table (3) reveals comprehensive data on the participants' awareness regarding the potential ocular side effects of oral isotretinoin (Roaccutane), a widely prescribed medication used for the treatment of acne. The data showcases the varying levels of knowledge among the participants, highlighting both the strengths and gaps in their understanding of this important subject. The table indicates that most participants (64.4%) were aware that oral isotretinoin can cause dryness of the eyes, while a significant proportion (32.9%) were unaware of this side effect. This finding suggests that patient education and awareness campaigns have been moderately successful in disseminating information about this ocular side effect. However, the data also reveals that a smaller percentage of participants were aware of other potential ocular side effects, such as itchiness (50.2%), burning sensation (45.7%), blurred vision (33.2%), decreased dark adaptation (25.6%), refractive change (26.6%), intolerance to contact lenses (39.4%), and eyelid inflammatory conditions (34.9%). These statistics highlight the need for more comprehensive education and communication efforts to ensure that patients are fully informed about the range of ocular side effects associated with oral isotretinoin treatment. Interestingly, the data shows that a significant proportion of participants (68.5%) expressed a desire to learn more about the ocular side effects of oral isotretinoin, indicating a strong interest and willingness to enhance their knowledge in this area. This presents an opportunity for healthcare providers and pharmaceutical companies to develop and deliver targeted educational resources and interventions to address the identified knowledge gaps and empower patients to make informed decisions about their treatment. Overall, the data from this study provides valuable insights into the current state of patient awareness regarding the ocular side effects of oral isotretinoin and highlights the need for continuous efforts to improve patient education and communication in this critical area of dermatological and ophthalmological care.

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Table (3): participants awareness regarding isotretinoin (n=578).

Parameter		***No.***	***Percent (%)***
Oral isotretinoin (Roaccutane) can cause dryness of the eyes.	Yes	372	64.4
	No	190	32.9
	I don't know	16	2.8
Oral isotretinoin (Roaccutane) can cause itchiness of the eyes.	Yes	290	50.2
	No	264	45.7
	I don't know	24	4.2
Oral isotretinoin (Roaccutane) can cause burning sensation in the eyes.	Yes	264	45.7
	No	280	48.4
	I don't know	34	5.9
Oral isotretinoin (Roaccutane) can cause blurred vision.	Yes	192	33.2
	No	358	61.9
	I don't know	28	4.8
Oral isotretinoin (Roaccutane) can cause decreased dark adaptation.	Yes	148	25.6
	No	394	68.2
	I don't know	36	6.2
Oral isotretinoin (Roaccutane) can cause refractive change in the eye.	Yes	154	26.6
	No	394	68.2
	I don't know	30	5.2
Oral isotretinoin (Roaccutane) can cause intolerance to contact lenses.	Yes	228	39.4
	No	318	55.0
	I don't know	32	5.5
Oral isotretinoin (Roaccutane) can cause eyelid inflammatory conditions.	Yes	202	34.9
	No	354	61.2
	I don't know	22	3.8
Do you want to know more about oral isotretinoin (Roaccutane) ocular side effects?	Yes	396	68.5
	No	182	31.5

The data presented in Table 4 provides valuable insights into the levels of knowledge regarding isotretinoin intake among the study population. The findings indicate that a significant portion of the respondents, accounting for 42.6% of the sample, demonstrated a high level of knowledge about this medication. This suggests that educational efforts and awareness campaigns have been effective in disseminating critical information about the appropriate use and potential risks associated with isotretinoin. However, it is noteworthy that a sizable proportion of the participants, approximately 33.6%, exhibited a moderate level of knowledge, while 23.9% were classified as having a low level of understanding. This distribution highlights the need for continued efforts to enhance the overall knowledge and understanding of isotretinoin intake within the target population. By addressing the knowledge gaps and ensuring a more comprehensive understanding of this medication, healthcare professionals can better support patients in making informed decisions and managing their treatment

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effectively. The insights gained from this data can inform the development and implementation of targeted educational interventions, ultimately contributing to improved patient outcomes and adherence to isotretinoin-based therapies.

Table (4): Shows knowledge about isotretinoin intake score results.

	Frequency	**Percent**
High level of knowledge	246	42.6
Moderate level	194	33.6
Low level	138	23.9
Total	578	100.0

The data presented in the table provides valuable insights into the level of awareness among individuals regarding the intake of isotretinoin, a medication commonly used to treat severe acne. The results indicate that a significant proportion of the population (67.8%) exhibits poor awareness, which raises concerns about the potential risks associated with the improper use or administration of this medication. This finding underscores the importance of educational campaigns and targeted interventions to enhance public understanding of the appropriate use of isotretinoin, its potential side effects, and the necessary precautions to be taken during the treatment process. Furthermore, the relatively low percentage of individuals with high awareness (22.1%) suggests that healthcare professionals and regulatory authorities should prioritize the dissemination of accurate and comprehensive information to both patients and healthcare providers, ensuring that informed decisions are made regarding the utilization of this medication. By addressing the gaps in awareness, healthcare practitioners and policymakers can work towards improving the overall management of acne conditions and promoting better patient outcomes.

Table (5): Shows awareness about isotretinoin intake score results.

	Frequency	**Percent**
High awareness	128	22.1
Moderate awareness	58	10.0
Poor awareness	392	67.8
Total	578	100.0

Table (6) shows that the knowledge level regarding isotretinoin intake has statistically significant relation to gender (p value=0.0001), age (p value=0.0001), region of residence (p value=0.013), occupation (p value=0.001) and whether the participants had taken isotretinoin (p value=0.0001). It also shows statistically insignificant relation to education level.

Table (6): Relation between knowledge level and sociodemographic characteristics.

Parameters		***Knowledge level***		***Total (N=578)***	***P value****
		High level	**Moderate or low**		
Gender	Female	220	240	460	0.0001
		89.4%	72.3%	79.6%	

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	Male	26	92	118	
		10.6%	27.7%	20.4%	
Age	21 or less	86	76	162	0.0001
		35.0%	22.9%	28.0%	
	21 to 24	70	74	144	
		28.5%	22.3%	24.9%	
	24 to 40	52	110	162	
		21.1%	33.1%	28.0%	
	more than 40	38	72	110	
		15.4%	21.7%	19.0%	
Education level	Middle school	2	2	4	0.379
		0.8%	0.6%	0.7%	
	High school	36	48	84	
		14.6%	14.5%	14.5%	
	Diploma	14	32	46	
		5.7%	9.6%	8.0%	
	Bachelor's degree	186	234	420	
		75.6%	70.5%	72.7%	
	Postgraduate	8	16	24	
		3.3%	4.8%	4.2%	
Marital status	Single	174	184	358	N/A
		70.7%	55.4%	61.9%	
	Married	68	138	206	
		27.6%	41.6%	35.6%	
	Divorced	2	10	12	
		0.8%	3.0%	2.1%	
	Widowed	2	0	2	
		0.8%	0.0%	0.3%	
Region of residence	Northern region	8	6	14	0.013
		3.3%	1.8%	2.4%	
	Southern region	88	120	208	
		35.8%	36.1%	36.0%	
	Central region	36	24	60	
		14.6%	7.2%	10.4%	
	Eastern region	104	156	260	
		42.3%	47.0%	45.0%	
	Western region	10	26	36	
		4.1%	7.8%	6.2%	
Occupation	Healthcare professional	98	90	188	0.001
		39.8%	27.1%	32.5%	
	Other	148	242	390	
		60.2%	72.9%	67.5%	
Have you ever taken oral isotretinoin (Roaccutane)?	No	162	266	428	0.0001
		65.9%	80.1%	74.0%	

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	Yes	84	66	150	
		34.1%	19.9%	26.0%	

P value was considered significant if ≤ 0.05.

Table (7) shows that the awareness level regarding isotretinoin intake has statistically significant relation to gender (p value=0.002) and region of residence (p value=0.040). It also shows statistically insignificant relation to age, occupation and whether the participants had taken isotretinoin.

Table (7): Relation between awareness level and sociodemographic characteristics.

Parameters		***Awareness level***		***Total (N=578)***	***P value****
		High or moderate	**Poor**		
Gender	Female	162	298	460	0.002
		87.1%	76.0%	79.6%	
	Male	24	94	118	
		12.9%	24.0%	20.4%	
Age	21 or less	48	114	162	0.663
		25.8%	29.1%	28.0%	
	21 to 24	52	92	144	
		28.0%	23.5%	24.9%	
	24 to 40	52	110	162	
		28.0%	28.1%	28.0%	
	more than 40	34	76	110	
		18.3%	19.4%	19.0%	
Education level	Middle school	0	4	4	N/A
		0.0%	1.0%	0.7%	
	High school	24	60	84	
		12.9%	15.3%	14.5%	
	Diploma	14	32	46	
		7.5%	8.2%	8.0%	
	Bachelor's degree	144	276	420	
		77.4%	70.4%	72.7%	
	Postgraduate	4	20	24	
		2.2%	5.1%	4.2%	
Marital status	Single	114	244	358	N/A
		61.3%	62.2%	61.9%	
	Married	70	136	206	
		37.6%	34.7%	35.6%	
	Divorced	2	10	12	
		1.1%	2.6%	2.1%	
	Widowed	0	2	2	
		0.0%	0.5%	0.3%	
Region of residence	Northern region	6	8	14	0.040
		3.2%	2.0%	2.4%	

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	Southern region	78	130	208	
		41.9%	33.2%	36.0%	
	Central region	16	44	60	
		8.6%	11.2%	10.4%	
	Eastern region	70	190	260	
		37.6%	48.5%	45.0%	
	Western region	16	20	36	
		8.6%	5.1%	6.2%	
Occupation	Healthcare professional	68	120	188	0.154
		36.6%	30.6%	32.5%	
	Other	118	272	390	
		63.4%	69.4%	67.5%	
Have you ever taken oral isotretinoin (Roaccutane)?	No	132	296	428	0.244
		71.0%	75.5%	74.0%	
	Yes	54	96	150	
		29.0%	24.5%	26.0%	

P value was considered significant if ≤ 0.05.

Discussion:

Acne vulgaris is a prevalent skin condition that impacts approximately 9.4% of the global population, especially among young adults and teenagers. Oral isotretinoin is commonly prescribed as a primary treatment for severe cases of acne vulgaris due to its proven effectiveness and generally safe profile [19]. However, it can lead to ocular complications like dry eye disease, blepharitis, and conjunctivitis, with blepharoconjunctivitis being the most frequently reported adverse effect affecting 20%-50% of patients. In some cases, more severe ocular issues such as retinal dysfunction and papilledema have been documented [20]. Despite these potential side effects, there is a concerning lack of awareness among individuals undergoing isotretinoin therapy. Research conducted in the western region of Saudi Arabia indicated that a significant proportion (15%-50%) of patients were unaware of the ocular side effects associated with isotretinoin treatment [21]. Thus, we aimed in this study to measure the knowledge and awareness level among Saudi Arabia population about ocular side effects of oral isotretinoin.

As regard knowledge score about isotretinoin side effects, we have found that 42.6% of the sample, demonstrated a high level of knowledge about this medication. However, it is noteworthy that a sizable proportion of the participants, approximately 33.6%, exhibited a moderate level of knowledge, while 23.9% were classified as having a low level of understanding. Regarding the awareness score (67.8%) exhibits poor awareness, which raises concerns about the potential risks associated with the improper use or administration of this medication. However, 10% exhibits moderate awareness and 22.1% exhibited high awareness. Moreover, most participants (64.4%) were aware that oral isotretinoin can cause dryness of the eyes. Additionally, smaller percentage of participants were aware of other potential ocular side effects, such as itchiness (50.2%), burning sensation (45.7%), blurred vision (33.2%), decreased dark adaptation (25.6%), refractive change (26.6%), intolerance to contact lenses (39.4%), and eyelid inflammatory conditions (34.9%). 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

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media (41.8%) [22]. On the contrary, a study conducted among the Al-Madinah population reported satisfactory knowledge about isotretinoin, 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 [23,24]. Furthermore, a study conducted by Al-Aqaba et al. (2015) [25] found that only 45% of Saudi patients' prescribed oral isotretinoin were aware of its potential ocular side effects. Furthermore, only 30% of them were knowledgeable about the specific ocular complications associated with this medication, such as dry eye syndrome and blurred vision. Another study by AlEnezi et al. (2018) [26] reported similar findings, with only 38% of Saudi patients using oral isotretinoin showing adequate knowledge about its ocular side effects. Additionally, the study revealed that 22% of the participants experienced ocular symptoms while on isotretinoin, suggesting a disconnect between awareness and actual experiences of side effects among this population. Similar to our study results, a study by Sharma et al. (2019) [27] aimed to assess the knowledge and awareness of oral isotretinoin's ocular side effects among the general population in India. The study surveyed 500 individuals, of which only 35% were aware of the potential ocular side effects of oral isotretinoin. Among this group, 62% knew that dry eyes were a common ocular side effect, while only 24% were aware of the risk of blurry vision associated with the medication. In another study conducted by Singh et al. (2020) [28], showed that only 21% of the participants were aware of the potential ocular side effects of oral isotretinoin. Among those who were aware, 45% identified dry eyes as a common side effect, while only 15% recognized blurry vision as a potential risk. On the other hand, a study conducted by Smith et al. (2019) [29] found that only 42% were aware that isotretinoin can cause ocular side effects such as dry eyes and blurred vision. Furthermore, only 25% of participants knew that regular eye examinations are recommended during isotretinoin therapy to monitor for these side effects. In contrary, a study by Brown and Lee (2020) [30] investigated the awareness of oral isotretinoin's ocular side effects among 300 individuals in the United States. The results showed that 65% of the participants were unaware of the potential ocular side effects associated with isotretinoin use. Additionally, only 15% of the participants knew that isotretinoin could lead to serious eye conditions such as keratitis and conjunctivitis. These findings highlight the inadequate knowledge and awareness of oral isotretinoin's ocular side effects among the general population in the United States.

Conclusion:

In conclusion, the study conducted in Saudi Arabia to assess the knowledge and awareness of ocular side effects of oral isotretinoin revealed a mixed level of understanding among the population. While 42.6% of participants demonstrated a high level of knowledge about isotretinoin side effects, a significant portion showed only moderate (33.6%) or low (23.9%) levels of understanding. The awareness score indicated that 67.8% had poor awareness, with only 10% demonstrating moderate awareness and 22.1% exhibiting high awareness. The most commonly recognized ocular side effect was dryness of the eyes, while awareness of other potential side effects such as itchiness, burning sensation, and blurred vision varied. The study emphasizes the need for improved education and awareness campaigns regarding the ocular side effects of isotretinoin to ensure safe and effective use of this medication among the Saudi population.

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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 that there are no conflicts of interest.

Informed consent:

Written informed consent was obtained from all individual participants included in the study.

Data and materials availability

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

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