

Evaluating Acne Patients' Experience with Isotretinoin: The Pharmacist's Role in Patient Safety and Education

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Abstract

Background: Isotretinoin is a highly effective treatment for severe acne but carries significant risks, including teratogenicity and psychiatric effects. Pharmacists are well-positioned to enhance patient safety through education and monitoring, yet their role remains underutilized. This study evaluated the experiences of patients with acne who used isotretinoin and assessed the role of pharmacists in improving safety and education.

Materials and Methods: A cross-sectional study was conducted in Zawia, Libya, from November to December 2024. The questionnaire was distributed to the general population, targeting 122 oral isotretinoin users who were acne patients undergoing isotretinoin therapy. Data were collected on demographics, information sources, awareness of side effects, and pharmacist involvement, and were analyzed using SPSS version 26 with descriptive statistics (frequencies and percentages).

Results: Participants were predominantly female (59.8%) and aged 20–30 years. While (68%) received information about isotretinoin from physicians, only (39.3%) cited pharmacists as their primary source. Most patients (85.2%) were aware of side effects, with dry skin (89.4%) being the most common. Although (86.1%) had regular consultations, only (52%) received detailed pharmacist counseling. Critical gaps were identified in contraception (e.g., iPledge requirements), mental health monitoring, and laboratory follow-up. While (73.8%) acknowledged pharmacists as part of their care team, just (45.1%) perceived their input as effective.

Conclusions: Pharmacists play an important role in ensuring isotretinoin safety, yet their involvement remains inconsistent. Implementing standardized counseling protocols, especially for high-risk areas such as pregnancy prevention and mental health, could enhance therapeutic outcomes. Systematically integrating pharmacists into acne care teams may help close existing educational gaps.

Keywords: Isotretinoin, acne vulgaris, pharmacist counseling, patient safety, Libya.

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INTRODUCTION

As the largest organ in the body, the skin serves as a vital barrier and performs sensory, thermal regulation, and protective functions.¹ Among the many dermatological conditions, acne vulgaris (AV) is among the most prevalent, affecting nearly 9.4% of the global population. It is characterized by follicular blockage, excessive

sebum production, *Cutibacterium acnes* proliferation, and inflammation. AV is most common during adolescence but can persist into adulthood, particularly among women, and is associated with significant psychosocial consequences such as anxiety, depression, and reduced quality of life.^{2,3}

Treatment options vary according to the severity of infection, ranging from topical therapies and systemic antibiotics to hormonal treatments and oral isotretinoin.⁴ Isotretinoin is a vitamin A derivative that was approved by the US Food and Drug Administration (FDA) in 1982 and remains the most effective therapy for severe, resistant acne. Its mechanism of action involves reducing sebaceous gland activity and normalizing keratinization.^{5,6} However, its use is limited by a wide range of adverse effects, including mucocutaneous, musculoskeletal, psychiatric, hepatic, and gastrointestinal complications, with teratogenicity representing the most serious concern. For this reason, isotretinoin therapy requires careful monitoring and patient counseling.^{7,8}

Pharmacists play a pivotal role in this process by providing patient education on safe use, adherence, laboratory monitoring, contraception, and avoidance of risk factors during treatment. Their involvement ensures improved therapeutic outcomes and minimizes medication-related harm.⁹ However, in Libya, particularly in Zawia, data on the patient's awareness of ISO therapy are lacking. This study, therefore, aims to evaluate acne patients' experiences with isotretinoin in Libya and to assess the pharmacist's role in promoting safe use and patient education.

MATERIALS AND METHODS

A cross-sectional study was conducted in Zawia, Libya, from November to December 2024. The questionnaire was distributed to the target population, which consisted of acne patients from the general community who were receiving oral isotretinoin therapy. The inclusion criteria included individuals aged 12 years or older who were currently using oral isotretinoin for acne treatment. A total of 122 participants were enrolled in the study. Data collected included demographic characteristics, sources of information regarding isotretinoin, awareness of its potential side effects, and the role of pharmacists in patient education and counseling. A structured questionnaire was developed to evaluate participants' knowledge and experience regarding the drug, as well as the role of pharmacists in their treatment. The

purpose of the study was explained to the acne patients, and a cover letter outlining the goals and the inclusion criteria was attached to the questionnaire. A pilot test was conducted with 20 participants to assess the tool's clarity, validity, and feasibility. Based on the results of this pilot study, the questionnaire was modified to improve clarity, refine question phrasing, and ensure that it was concise and easy to understand. The final version of the questionnaire was then completed and prepared for distribution.

The final questionnaire consisted of the following sections:

1. Demographic Data: Age, gender, marital status, and education level.
2. Isotretinoin experience: Questions assessing participants' knowledge of isotretinoin use, potential side effects, and safety precautions.
3. Pharmacists' Role: Questions evaluating patients' experiences with pharmacist counseling and satisfaction with the information provided. The questionnaire was designed to take approximately 10 minutes to complete and was provided in Arabic to get a faster response.

A total of 134 patients were approached, of whom 122 completed questionnaires were included in the final analysis, while 12 incomplete responses were excluded.

Data were collected through in-person interviews using a structured questionnaire, and then analyzed using SPSS version 26 using descriptive statistics (frequencies and percentages).

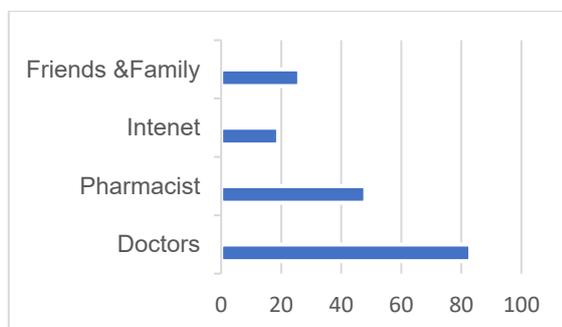
RESULTS

The study included 122 participants who had previously treated skin conditions with oral isotretinoin and successfully finished the survey. It was found that 73 (59.8%) of females, 49 (40.2%) of males, and 59 (48.4%) of study participants aged between 20 and 30 years old 87 (71.3%) were single. Regarding education, the majority, 63 (51.6%) of the sample participants were university students, followed by 36 (29.5%) in secondary school, 20 (16.4 %) had diplomas, and only 3 (2.5%) were postgraduate, [Table 1](#).

Table 1. Sociodemographic characteristics of participants (n, %).

Characteristics	Number and percentage of patients (n, %)
Gender	
Female	73 (59.8%)
Male	49 (40.2%)
Age	
12-20 years	52 (42.6%)
20-30 years	59 (48.4%)
Above 30 years	11 (9.0%)
Marital Status	
Single	87 (71.3%)
Married	35 (28.7%)
Educational level	
University	63 (51.6%)
Postgraduate	3 (2.5%)
Diploma	20 (16.4%)
Secondary school	36 (29.5%)

All participants in this study (n= 122) had used isotretinoin. The majority, 83 (68%) of participants gained knowledge about isotretinoin from their doctors, followed by pharmacists, 48 (39.3%). A smaller proportion relied on the Internet 19 (15.6%) or friends and family 26 (21.3%). Participants were allowed to select more than one source of information. The information source distribution is shown in Figure 1.

**Figure 1:** Participant's isotretinoin information source.

Most participants, 112 (91.8%), received information before starting treatment, while 10 (8.2%) did not receive any prior guidance.

104 (85.2%) of participants were aware of potential side effects. Among them, the most frequently reported side effects were dry skin 93 (89.4%), sun sensitivity 38 (36.5%), mood changes 36 (34.6%), and birth defects 33 (31.7%). Rarely mentioned side effects included hair loss 1 and dry eyes 1 (1% each). Acne patients' awareness and preparation before

treatment, and their knowledge of isotretinoin's adverse effects are illustrated in Table 2.

Most participants, 105 (86.1%), reported regular consultations throughout their treatment, while 17 (13.9%) did not have consistent follow-ups. Among those who had consultations, 45 (43%) consulted a doctor, 24 (23%) relied on a pharmacist, and 36 (34%) received guidance from both a doctor and a pharmacist.

Regular sources of consultations during treatment are illustrated in Table 3.

Among the participants, 63 (52%) reported that pharmacists provided detailed information regarding the side effects of isotretinoin. An additional 32 (26%) received partial information, while 27 (22%) stated that pharmacists did not provide any information on potential adverse effects.

The pharmacist's role in providing guidance and safety advice is illustrated in Table 4.

DISCUSSION

The results of this study shed light on the knowledge and experiences of acne patients undergoing isotretinoin therapy, as well as the role of pharmacists in their treatment journey. Most participants were young, educated, and unmarried, which aligns with the typical demographic of the acne-affected community. Female participants represented a larger proportion of the sample compared to males, this is consistent with global trends, as females are more likely to seek treatment for acne due to social and cosmetic concerns. Additionally, most participants fell within the 12–30 age range,

Table 2. Awareness and preparation before treatment.

Parameters	Number and percentage of patients (n, %)
Did you receive information before treatment?	
Yes	112 (91.8%)
No	10 (8.2%)
Awareness of side effects	
Yes	104 (85.2%)
No	18 (14.8%)
Most commonly reported side effects (among 104 aware participants)	
Dry skin	93 (89.4%)
Sun sensitivity	38 (36.5%)
Mood changes	36 (34.6%)
Birth defects	33 (31.7%)
Hair loss	1 (1.0%)
Dry eyes	1 (1.0%)

Table 3. Regular and source consultation during treatment.

Parameter	Number and percentage of patients (n, %)
Did you receive regular consultations during the treatment period?	
Yes	105 (86.1%)
No	17 (13.9%)
Source of consultation	
Doctor	45 (43%)
Pharmacist	24 (23%)
Both the doctor & pharmacist	36 (34%)

Table 4. The pharmacist's role in providing guidance and safety advice.

Questions	Number and percentage of patients. (%)
Did you receive information about the isotretinoin side effects from the pharmacist?	
Yes, in detail	63 (52 %)
Yes, partially	32 (26 %)
No	27 (22 %)
Have you received instructions to check your blood levels of cholesterol and liver function?	
Yes	71 (58.2%)
No	51 (41.8%)
Have you been instructed to stop using the medication if severe side effects occur?	
Yes	82 (67 %)
No	40 (33 %)
Did the pharmacist advise you to take the medicine after a heavy meal?	
Yes	56 (45.9%)
No	66 (54.1%)
Did your pharmacist inform you that blood donation is not allowed during isotretinoin treatment?	
Yes	58 (47.5%)
No	64 (52.5%)

Did the pharmacist advise you to see a doctor if there was any change in mood or behavior?	
Yes	69 (57 %)
No	53 (43 %)
Did your pharmacist advise you to use a face and lip moisturizer and sunscreen?	
Yes	92 (75.4%)
No	30 (24.6%)
(Among female participants, N= 73)	
Did your pharmacist advise you to avoid using hair removal methods, whether laser or wax?	
Yes	40 (54.8%)
No	33 (45.2%)
If you are of childbearing age, has the pharmacist advised you to use contraception during treatment?	
Yes	45 (61.6%)
No	28 (38.4%)
Did your pharmacist advise you to avoid using the medication while breastfeeding?	
Yes	34 (46.6%)
No	39 (53.4%)

Table 5. Patients' satisfaction with the information and consultation provided by the pharmacist.

Questions	(%) .Number and percentage of patients
Do You Feel the Pharmacist Was Part of Your Healthcare Team During Treatment?	
Yes	90 (73.8%)
No	32 (26.2%)
Do You Think the Pharmacist Played an Effective Role in Guiding Your Skincare During Treatment?	
Yes, they were effective	55 (45.1%)
Yes, but their role was limited	53 (43.4%)
No, they did not play a role	14 (11.5%)

which aligns with previous studies indicating that acne primarily affects teenagers and young adults. In 2021, young women exhibited an approximately 25% higher age-standardized prevalence rate of acne vulgaris than young men.¹⁰ The study involved 122 participants who previously used oral isotretinoin. The main sources of information about isotretinoin among participants demonstrated a clear reliance on healthcare professionals. Physicians were identified as the primary source of information, underscoring the vital role that healthcare professionals play in educating patients about this medication. This is in line with best practices, as physicians are well-equipped to provide comprehensive information on isotretinoin's benefits, risks, and necessary

precautions, and consistent with a previous study that found the most frequent source of information for acne patients was their doctors.¹¹ Such reliance reflects the structured nature of medical consultations, where isotretinoin's indications, monitoring requirements, and safety considerations are typically discussed in detail.

Pharmacists were the second most common source of information, reinforcing their role as accessible healthcare providers who can counsel patients on medication use and safety. The fact that people have a lower dependence on pharmacists than doctors may suggest that isotretinoin is more frequently discussed during medical consultations than at the point of dispensing.

Interestingly, only a small proportion of participants reported using the Internet as a source of information. Although online platforms can provide accessible health content, the preference for direct professional guidance may reflect patient trust in healthcare providers and awareness of the risks of misinformation. Similarly, information obtained from friends and family, while potentially supportive, may lack medical accuracy. These findings collectively underscore the importance of ensuring that patients receive clear, evidence-based counseling from qualified healthcare professionals to promote safe and informed use of isotretinoin.

According to the study's findings, most participants received information before starting isotretinoin treatment, demonstrating that healthcare providers typically ensure patients are informed about the medication. However, a small proportion did not receive prior guidance, highlighting a gap that could potentially lead to misuse or unawareness of critical safety measures. Ensuring that all patients receive comprehensive pre-treatment counseling is essential for optimizing adherence and minimizing risks.

The majority of participants reported being aware of the potential adverse effects of isotretinoin, suggesting that patient education through healthcare professional counseling or medication leaflets effectively conveys common safety information. Dry skin was the most frequently recognized side effect, reflecting the well-known impact of isotretinoin on sebaceous gland activity and consistent with previous studies.¹¹ Other commonly noted effects, such as sun sensitivity and mood changes, highlight areas where patients may require additional guidance to manage daily activities and mental well-being during treatment. Awareness of serious but less common effects, such as the teratogenic risk of isotretinoin, was acknowledged by a smaller proportion of participants. This finding underscores the importance of emphasizing high-risk adverse effects during counseling, particularly for female patients of childbearing potential. Rare side effects, including hair loss and dry eyes, were less frequently reported, suggesting that healthcare providers tend to prioritize the most

clinically relevant or prevalent effects in patient education.

These results highlight a critical role for pharmacists in reinforcing awareness of both common and high-risk side effects. By providing targeted counseling, pharmacists can ensure patients receive comprehensive safety information, improve adherence, and reduce preventable adverse outcomes. This emphasizes the need for structured pharmacist-led education protocols that cover both routine and critical safety considerations for isotretinoin therapy. The findings reveal that a majority of participants received consistent consultations during isotretinoin treatment, aligning with the medication's need for careful monitoring due to its serious risks. However, the absence of regular follow-ups in some patients highlights a critical gap in care, potentially leaving these individuals vulnerable to undetected adverse effects.

Healthcare providers played distinct yet complementary roles in patient education. While doctors served as the primary advisors, pharmacists also contributed significantly: nearly one-quarter of patients relied solely on pharmacists, and over one-third engaged with both professionals. This highlights the importance of collaboration between doctors and pharmacists in providing comprehensive patient care.

Variation was observed in the extent and depth of pharmacist counseling provided to patients initiating isotretinoin therapy. While some participants reported receiving comprehensive explanations of potential adverse effects, others indicated that no counseling was provided. Such inconsistency may result in uneven patient understanding of critical risks, including teratogenicity and possible psychiatric effects. Given the safety profile of isotretinoin, variability in counseling practices represents a significant concern and highlights the absence of standardized communication protocols.

Although most patients received advice regarding supportive measures such as the use of moisturizers and sunscreen, appropriate recommendations considering the drug's well-known association with skin dryness and photosensitivity, important safety instructions were not uniformly delivered. A notable

proportion of patients reported not being informed about potential side effects or advised to discontinue therapy and seek medical attention if serious adverse reactions occurred. These gaps are particularly concerning in light of isotretinoin's association with hepatotoxicity, hyperlipidemia, and psychiatric symptoms, which require timely recognition and monitoring.

Interestingly, Patients were not adequately encouraged to monitor blood cholesterol and liver function, despite the importance of these tests for the early detection of metabolic complications. Likewise, less than half of the patients were instructed to take the medication after a heavy meal, even though isotretinoin is lipophilic and its absorption is enhanced when taken with fatty food. Although more than half of the participants were advised to seek medical attention if they experienced mood changes, an essential precaution given the association between isotretinoin and depression or anxiety, a considerable proportion still did not receive this guidance. In addition, many patients were not informed about the need to avoid blood donation during treatment, which poses a potential risk of transferring the drug to others, particularly pregnant women. This finding differs from a previous study in which the majority of respondents reported being informed about abstaining from blood donation.¹²

Gender-specific counseling revealed notable inconsistencies. A considerable proportion of female participants reported not being advised to use contraception during treatment, and many received no guidance regarding the avoidance of breastfeeding while taking isotretinoin, despite its well-established teratogenic risk. Although just over half were cautioned against certain hair removal methods, a substantial number remained uninformed, potentially increasing the risk of skin irritation and damage.

These findings highlight the need for standardized pharmacist-led counseling protocols to ensure the consistent delivery of essential safety information. Greater emphasis on high-risk areas such as pregnancy prevention and required laboratory monitoring, along with addressing gaps in patient education, could significantly enhance medication safety and adherence. Pharmacists

have a central role in minimizing the risks associated with isotretinoin, and structured training programs may help improve the comprehensiveness and consistency of counseling practices.

With regard to patient satisfaction, the majority of participants reported feeling that the pharmacist was an integral part of their healthcare team during treatment. This is consistent with findings from a previous study in which most participants expressed satisfaction with the information provided during clinical consultations.¹³ These results reinforce the important role of pharmacists in patient care. Nevertheless, a notable proportion of patients did not share this perception, indicating existing gaps in communication and support that warrant further attention and improvement.

Opinions regarding skincare guidance were varied. Less than half of the patients felt that the pharmacist played an effective role in this aspect of care, while a similar proportion perceived the pharmacist's role as limited. A smaller group reported not receiving any assistance with skincare management. These findings indicate that although pharmacists provide some level of support, their involvement in skincare counseling during isotretinoin therapy could be strengthened. Enhancing pharmacist-patient communication and expanding the pharmacist's role in offering clear, practical skincare advice may improve patient satisfaction and, in turn, overall treatment outcomes. The study was limited by its cross-sectional design, relatively small sample size, and restriction to a single geographic area, which may affect the generalizability of the results. Additionally, the use of descriptive statistics without inferential analysis may limit the strength of the conclusions.

CONCLUSION

This study reaffirms the pivotal role of pharmacists in the management of acne patients undergoing isotretinoin therapy. While physicians primarily provided initial medical counseling, pharmacists made significant contributions by educating patients on adverse effects, proper medication use, and skincare management. However, essential aspects such

as contraception counseling, blood donation restrictions, and mental health monitoring were frequently underemphasized. The finding of moderate patient satisfaction highlights the ongoing need for a structured, comprehensive, and patient-centered pharmaceutical care model to optimize therapeutic outcomes and ensure medication safety. Accordingly, standardized counseling protocols should be implemented to ensure consistent communication of critical safety information, particularly regarding teratogenicity and psychological well-being. Moreover, formally integrating pharmacists into dermatology care teams could enhance interdisciplinary collaboration and continuity of care. Raising awareness among patients and healthcare professionals about isotretinoin's significant adverse effects and required safety measures, alongside establishing a national monitoring framework to oversee pregnancy prevention, laboratory testing, and safe dispensing practices, would collectively strengthen the overall safety and effectiveness of isotretinoin therapy.

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