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ORIGINAL RESEARCH

Proper Counseling and Dispensing of Isotretinoin Capsule Products by Community Pharmacists in UAE: A Simulated Patient Study

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Purpose: To evaluate the pharmacist's assessment of patient eligibility for safe use of isotretinoin and the quality of pharmacist's counseling.

Patients and Methods: A covert simulated patient (SP) methodology was used in which a trained female researcher, who was 25 years old, played the patient's role through this cross-sectional study by visiting community pharmacies and requesting isotretinoin capsules through a controlled prescription. A data form was used to collect the information following each pharmacy visit by asking about medical/family history and providing comprehensive counseling about the most common adverse effects, proper use instructions, and the importance of adherence to medication. The pharmacists, who did not initiate counseling, were prompted by the SP.

Results: The pharmacists in 400 pharmacies who agreed to participate were visited by the SP. Only 7 (2%) pharmacists provided a complete assessment of patient eligibility for using isotretinoin with comprehensive counseling. Most of the pharmacists (84%) provided incomplete assessment as indicated by the overall score. Only 11 (3%) pharmacists asked the six crucial questions for the assessment of patient eligibility. On prompting, only 6 (2%) pharmacists provided complete counseling about the expected adverse effects. The most frequently provided adverse effect was dry skin, specifically dry lips (71.8%). A minority of 108 (27%) pharmacists provided education about the importance of using contraception during isotretinoin therapy. A complete level of counseling was provided by 125 (31.3%) pharmacists regarding the lab tests that the SP needs to undergo during therapy. Female pharmacists were more likely to provide counseling about the pregnancy test (mean=134, p=0.001).

Conclusion: Suboptimal level of the patient's assessment was revealed with poor educational counseling by the community pharmacists. New strategies are needed to improve pharmaceutical care services in the UAE.

Keywords: community pharmacy services, patient simulation, counseling, birth defects

Introduction

The American Academy of Dermatology describes acne as the most common skin condition in the United States, affecting up to 50 million Americans yearly.[1] The prevalence of acne in France was estimated to be 60% among women aged 20–29 years and 26% in those aged 40–49 years.[2] Numerous studies worldwide reported that acne has considerable effects on patients' quality of life (QOL).[3,4] Treatment of acne depends on the severity and it may take several months of treatment before the symptoms improve. Patients suffering from severe nodular acne that has not

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responded to other treatments including antibiotics are mostly treated with isotretinoin. It is a natural derivative of vitamin A and one of the most effective medications used to treat acne since its introduction to the market at the beginning of 1982. On the other hand, it carries such serious risk because of the serious side effects including teratogenicity.[5] To reduce or prevent adverse drug reactions and complications associated with isotretinoin especially the teratogenicity effect, risk management programs have been provided such as: Pregnancy Prevention Program (PPP) that has been recently updated and iPLEDGE in the USA.[6] They help ensure that isotretinoin benefits outweigh the risks and ensure safe use by patients. Within these programs, isotretinoin must only be prescribed/dispensed by the physicians/pharmacists who are registered and activated in the program. The medicine will be dispensed only for patients who meet all the restrictions encompassed in each program.[7,8]

Pharmaceutical care focuses on different important aspects related to pharmacists such as their behaviors, attitudes, concerns, knowledge, and skills in delivering drug information to achieve successful treatment outcomes.[9] Patients should be provided with comprehensive information about the medicine they will use.[10] One study showed that dermatologist counseling to women in reproductive age was very poor. They did not provide them with adequate information about the teratogenic effect of isotretinoin.[11] Instead, certain papers revealed that the pharmacist educated the patients properly and provided them with sufficient knowledge to recognize the risks associated with their medication by using specific programs such as iPLEDGE.[12–14]

There is a gap between the proven efficacy of isotretinoin capsules that are prescribed by a dermatologist in the clinic and their actual effectiveness in practice.[15] As health-care professionals, pharmacists play an important role in improving access to proper medicines and in filling the gap.[16,17] The consequences of low medication adherence to anti-acne treatment due to poor counseling and poor understanding of the proper use of the medicine result in additional unnecessary treatments, frustration, and increased medical expenses.[18] The pharmacists have to make sure that all instructions needed to use the medicine are clear.[16]

In the United Arab Emirates (UAE), the medicines are classified as narcotics (only available in the hospitals), controlled or psychotropic drugs, semi-controlled drugs, POM, Pharmacist-only medicine, OTC, and GSL. Two types of prescriptions are available first one for the non-controlled drugs and second one for controlled drugs classified as class A (narcotic and psychotropic) and class B (semi-controlled). A controlled drug prescription is required to purchase the isotretinoin capsules (class B controlled medicine). The controlled medication E-prescription platform (OPENjet) system is specially designed to administer the prescription and to manage the dispensing process of controlled, semi-controlled, and narcotic medications. The purpose of the OPENjet system is to allow the dermatologist to create the prescription and send it to the pharmacist for dispensing the medicine via an internal web. This system can be accessed by only two end-users, the prescriber (authorized dermatologist) who prescribes the semi-controlled medicine using the platform then the dispenser (licensed pharmacist) who dispenses the prescribed medicine to the patients.[19]

The general objective of this study was to assess the isotretinoin dispensing and counseling process provided by community pharmacists in UAE. More specific objectives were to evaluate the pharmacist`s assessment of the patient eligibility for the safe and effective use of isotretinoin and to determine the quality of pharmacist`s counseling and advice-giving that were provided to the SP. This was the first study to assess proper dispensing and counseling provided by community pharmacists about isotretinoin capsules in UAE.

Patients and Methods

Study Design and Setting

Data collection was carried out between June and September 2019 in community pharmacies across the UAE by a single covert simulated patient (SP) in a cross-sectional study. A month before the SP visiting the pharmacies, the pharmacist in charge/manager was contacted by the researcher and informed that an SP would come to their pharmacies in the following weeks and his/her verbal consent was obtained. The pharmacist-in-charge who agreed to the visit by the simulated patient was given a phone number to call in case the simulated patient was detected. Authorized (licensed) pharmacies that keep controlled/semi-controlled medicines in UAE were included in this study. The female researcher was married 25 years old posed as an SP and looked worried from oily skin with acne on face and shoulders enacting a standardized scenario when pharmacies were visited to meet one pharmacist from each pharmacy. At the time of medicine

purchase, the SP would decide to rethink or learn more about the medical benefits versus harms before coming back to buy it. A controlled prescription was required to purchase oral isotretinoin capsules in all emirates including Abu Dhabi, Dubai, and north Emirates (Sharjah, Ajman, Umm Al Quwain, Ras Al Khaimah, and Fujairah). The prescriptions used in this study were from a dermatologist who was informed about the study's aims and agreed to write the prescriptions. As the controlled prescriptions are valid for three days only, thirteen prescriptions were written by the physician to cover the period of data collection. He was not reimbursed for this.

The Scenario

The study scenario involved a woman who is 25 years old and presented to the community pharmacy with a prescription of oral isotretinoin. She was married and in the childbearing age (SP Scenario). This scenario was chosen due to the high prevalence of female patients that were exposed to isotretinoin therapy.[20] Details of the simulated patient scenario can be found in appendix 1.

Female patients of reproductive age should perform a pregnancy test before receiving an isotretinoin prescription. Two forms of contraception (primary & secondary) should be concomitantly prescribed and dispensed during the isotretinoin course of treatment.[21] According to the risk management programs used in the USA and Europe, female patients must have two negative pregnancy tests before starting the use of medicine. The patient must repeat it each month before receiving a new prescription for the medicine refill. In addition, another test is requested after one month from the last dose of isotretinoin.[22] Table 1 summarizes the important criteria that were evaluated in this study. This scenario was standardized for all the visits, with the SP being instructed not to give additional information other than what the pharmacist asked for, and not to lead the pharmacist by asking questions. If the pharmacist failed to ask the appropriate questions or provide the desired information, the SP would then prompt him/her and ask for the information.

Pilot Study

A pilot study (PS) was conducted including ten pharmacies to assess the feasibility of the study. Pharmacy sites included in the pilot study were excluded from the study visits and the results were not included in the statistical data analysis. No modifications were done to the study scenario. All the pharmacies' visits were conducted by one

Table 1 Evaluation of the Pharmacist Performances Based on Whether Specific Information Was Collected/Provided from/to the Simulated Patient

Pharmacists' Assessment of the SP's Eligibility for Safe Use of Oral Isotretinoin Capsules	- Asking SP about Age
	- Pregnancy Status Screening Question
	- Laboratory Tests Checking Question
	- Family History, Chronic Illness and Medication/Supplement Use Screening Questions
Counseling and Education Provided by the Community Pharmacists	- Educational Intervention toward Adverse Drug Reactions
	- Counseling on Contraceptive Use
	- Counseling on Laboratory Test
	- Educational Counseling on Isotretinoin Use Instructions
	- Adherence Counseling

SP to ensure quality and similarity across SP visits. The SP received a two-hour training session by the primary investigator who has good experience in this type of research. The data was completed immediately after she had left the pharmacy to avoid missing any data by using a standard checklist (Data Collection Form). The collection form can be found in the supplementary materials (appendix 2).

Sampling

This was an observational study where representativeness is more significant than a large sample size. To ensure representativeness a stratified random sample technique was used. Reliable and valid sources such as the yellow pages (the official business contact directory) were used to obtain the contact numbers and locations of community pharmacies. In UAE, more than 2000 community pharmacies are available according to 2010 estimation.[23] Community pharmacies were stratified by Emirates and then the pharmacies from each Emirate were randomly sampled. The SP informed the in-charge pharmacist that the study's purpose was to assess community pharmacists' counseling and advice-giving without mentioning the medicine name (isotretinoin). About 510 community pharmacies were visited by the SP, 110 of them were

excluded as they were not authorized for dispensing controlled or semi-controlled medicines. Data collection was continued until information from 400 pharmacies was collected. This sample size is expected to yield reliable results compared to a similar SP study that covered UAE.[24]

Data Coding and Scoring System

The coding scheme was developed and employed to estimate the overall performance regarding dispensing the isotretinoin capsules. The only continuous data collected during each visit was the duration of the SP encounter with the pharmacist. General characteristic data of the pharmacies/pharmacists, data collected from the assessment questions, and data from which the pharmacist was provided self-initiated or prompted counseling were defined and entered all as categorical data. The quality rate of the educational counseling provided by the pharmacists was entered as ordinal data with coding scheme includes: Complete = 3, Incomplete = 2, Poor or incorrect information = 1.

Coding training and reliability were refined by coding the 10 pilot study visits. The coding was consistent and reliable as several meetings were held after data collection to agree on what constituted a code based on the patient information leaflet for isotretinoin produced by the British Association of Dermatologists.[25] Further details of the coding system can be found in the appendix 3.

Reference of Assessment

The mentioned items on the data collection form were obtained from the "Pharmacist's guide to dispensing Roaccutane® (isotretinoin)" and other published articles and guidelines for dispensing and counseling practices provided for community pharmacists regarding oral isotretinoin prescriptions.[26,27]

The pharmacists' assessment strategy for the patient`s eligibility for safe use of oral isotretinoin capsules was by:

1. Identifying the patient's medical history by asking about: age, chronic diseases, contraindicated conditions, and hypersensitivity reactions (vitamin A analogue or peanut/soya allergy).
2. Screening for female patient`s pregnancy status
3. Asking the patients about the currently used medication and supplements

The qualified pharmacists should provide counseling on:

1. The proper isotretinoin capsules use instructions
2. Emphasizing the importance of therapy compliance and what action plans should be taken in case of missed doses.
3. Providing the patients with information regarding the common adverse reactions that may occur during the isotretinoin course of therapy

Data Analysis

SPSS version 25 (IBM, New York, USA) was used to perform statistical data analysis. Descriptive statistical analysis was employed for normally distributed data. The total of assessment questions, quality rate of counseling, and overall performance of pharmacists were defined and analyzed in the SPSS as continuous data. Additionally, the inferential analysis was conducted by a chi-square test to check if there is a difference between the pharmacies in the seven Emirates that were visited during the study. The differences concerning the total number of assessment questions or with the total of counseling and education provided by the pharmacist were estimated by using the ANOVA test with post hoc test Tukey. *t*-test was used to determine the significant differences between the continuous data depending on general characteristics data of pharmacists/pharmacies (pharmacy location, pharmacist gender, pharmacy type, and the number of staff during the visit) that identified as categorical data. The adequacy of pharmacist`s counseling about the adverse drug reactions (ADRs), use instructions, contraceptive use, and monitoring laboratory tests were estimated by using the chi-square test. A binomial test was used to clarify if the pharmacists provided the SP with information related to the ADRs, whether they asked questions to assess the SP`s eligibility for safe use and to determine if there was a difference in pharmacist's gender or the community pharmacy type observed during the SP visits.

Ethical and Logistical Considerations

Ethical approval was received from the Research Ethics Committee at Ajman University, Reference No: P-F-H-19-05-06. Before the SP started visiting the pharmacies, Verbal informed consent was acceptable and approved by the Research Ethics Committee. The SP started visiting the pharmacies after a reasonable extended time (at least one

month) to prevent SP uncover by the pharmacist and to minimize bias. The collected information during the pharmacist encounter would not be reported in any way that would identify the pharmacy or the encountered pharmacist.[28] The ethical approval can be found in appendix 4.

Results

General Characteristics of the Community Pharmacies/Pharmacists

The pharmacists in the 400 pharmacies who agreed to participate in the study and authorized to keep controlled and semi-controlled medicine were later visited by the simulated patient (SP). None of the pharmacies called the provided phone number to the pharmacist-in-charge to report the detection of the simulated patient encounters. None of the conducted visits were excluded. Within the participating pharmacists, 52% (n=209) were females. More than half of the pharmacies (67%) were located in the northern emirates, while 15% were in Abu Dhabi and 18% in Dubai. Almost half of them (54%) were chain pharmacies. The number of staff observed by the SP during the visits was one pharmacist in 36% of the pharmacies (n=144), two pharmacists in 30% of the pharmacies (n=119), and three or more in 34% of the pharmacies (n=137).

Pharmacists' Assessment of the SP's Eligibility for Safe Use of Oral Isotretinoin Capsules

Only 11 (3%) pharmacists asked the six crucial questions for the assessment of patient's eligibility for safe and effective use. The statistical analysis showed that 38% of the pharmacists provided an incomplete level of safety assessment with 59% asking not more than two questions out of six. Pregnancy status screening question was the most frequently asked question by 211 (53%) pharmacists while other questions were less frequently asked. For examples, 140 (35%) pharmacists asked the SP about their age, 151 (38%) pharmacists checked if the patient was undergoing the required laboratory tests before receiving the isotretinoin prescription, 109 (27%) pharmacists asked about the medical history of the SP`s and the presence of chronic illness, 126 (32%) pharmacists asked about the medicines or supplements that were used at the time of the visit and the requirement for family history was checked by 133 (33%) pharmacists.

Counseling and Education Provided by the Community Pharmacists

Counseling and patient education regarding the most common side effects, proper capsule use instructions, the importance of using contraception while the female patient`s on isotretinoin therapy, and continuing the performance of the laboratory tests during the therapy course are needed. These were provided completely by 50 (13%) pharmacists. Most of the pharmacists (298, 75%) provided an incomplete level of counseling and 12% provided a poor level of educational counseling.

Unprompted counseling was provided by 142 (36%) pharmacists about the most common adverse effects that may occur during therapy (binomial test, p= 0.001). The most frequently provided adverse effect was dry skin, specifically dry lips (72%), followed by muscles and joint pain (64%), increased fat level in blood and mild liver inflammation (57%), sunburn (53%), the effect on vision at night (38%) and hair thinning and dryness (35%). None of the pharmacists indicated that isotretinoin capsules therapy is free from side effects. Only108 (27%) pharmacists provided self-initiated education about the importance of using two methods of contraception while receiving the isotretinoin capsules, 151 (38%) pharmacists provided counseling regarding the laboratory tests that the SP needs to undergo during therapy (binomial test, p=0.001) and 237 (59%) provided counseling on use instructions of oral isotretinoin capsules (binomial test, p= 0.001). Table 2 provides more details about the quality of educational counseling provided by the pharmacists.

An unsatisfactory level of counseling was provided regarding the adherence and action taken in case of

Table 2 Quality of Pharmacist's Counseling About Isotretinoin Therapy When Prompted

Item	Poor	Incomplete	Complete	Test/Significance
Quality of pharmacists counseling on how to use the capsules	76(19%)	215(53.8%)	109(27.3%)	Chi-square test P= 0.001*
Quality of pharmacists counseling about the laboratory tests	85(21.3%)	190(47.5%)	125(31.3%)	Chi-square test P= 0.001*
Quality of pharmacists counseling about side effects	167(41.8%)	227(56.8%)	6(1.5%)	Chi-square test P= 0.001*
Quality of pharmacist counseling about contraceptive	150(37.5%)	230(57.5%)	20(5%)	Chi-square test P= 0.001*

Note: *Significant difference > 0.001.

missing doses as only 154 out of 400 (39%) pharmacists provided the SP with unprompted educational information (binomial test, p=0.001). On prompting, 62% of the pharmacists counseled the SP properly about the importance of the treatment compliance and the right action to take in case of missed doses.

The Overall Performance Quality of Community Pharmacists

Pharmacists had an unacceptable level in providing the SP with comprehensive care regarding isotretinoin capsules prescription. Only 7 (2%) pharmacists provided a complete assessment of patient eligibility of using isotretinoin capsules and advice-giving for the SPs regarding the isotretinoin prescription. Most of the pharmacists (84%) provided incomplete assessment and counseling as indicated by the overall score.

The female pharmacists assessed the SP`s pregnancy status significantly more than male pharmacists (female=134, male=77, p=0.001, chi-square) and more likely to provide counseling about the pregnancy test (mean=134, p=0.001). In addition, the pharmacists in chain pharmacies were more likely to ask about the patient`s performance of the required laboratory tests (chain=104, individual=47, p=0.001, chi-square) and more likely to advise patients about avoiding sun exposure and the importance of using sun protection before sunlight exposure (mean = 127, p= 0.021, chi-square).

Discussion

In this study, the evaluation of the pharmacist assessment of female patient eligibility for safe use of isotretinoin and the quality of pharmacist`s counseling was carried out and found that only 7 (2%) pharmacists provided a complete assessment of patient eligibility for using isotretinoin with comprehensive counseling. Only 11 (3%) pharmacists asked the six crucial questions. On prompting, only 6 (2%) pharmacists provided complete counseling about the expected adverse effects. A review of the published literature showed that a small number of studies were carried out worldwide to evaluate the community pharmacist's competencies toward isotretinoin prescriptions.[29,30]

In UAE, during the SP visits, most of the pharmacists dispensed the medicine without a complete assessment of the patient`s eligibility for safe use. Systematic patient information was obtained by only 3% of the pharmacists which may lead to unacceptable health risk consequences to female patients.[31] Some disease conditions such as diabetes, osteomalacia, hyperlipidemia, and liver disorders will exacerbate if they were present with the use of the isotretinoin capsules concurrently. The pharmacists should exercise caution in these situations with careful monitoring.[22]

Poor level of pharmacist`s knowledge about the potentially serious effect of isotretinoin capsules in the case of pregnant women combined with poor compliance with the guidelines and recommendations may explain the inadequate assessment. In one study only 26 pharmacists out of 76 reported the contraindicated use of isotretinoin during pregnancy.[30] Moreover, it was shown that community pharmacists who did not properly assess female patients, were not aware of the potential risk of teratogenicity associated with the medicine.[29] Poor recognition and assessment of the patient`s safety were observed in our study as only 32% of the pharmacists asked about the medicines or supplements that were to be used with isotretinoin. This was in agreement with a study conducted in Iran using the SP methodology. Only fifteen out of the ninety- seven participating pharmacists identified isotretinoin-vitamin A interaction after the pharmacists being informed about the use of isotretinoin for severe acne.[32]

In our study, more than half of the pharmacists (59%) provided unprompted educational counseling about proper use. In contrast, counseling regarding the other aspects such as common ADRs, contraceptive use, laboratory test, and adherence were prompted by the SP rather than self-initiated by the participating pharmacists. Our results were comparable to a study conducted in Ghana in which pharmacists counseled the patients about the right use instructions such as quantity, frequency, and dosage of the prescribed medicines more than other aspects.[33] On the other hand, the patient's knowledge about medication safety was poor due to the insufficient education provided by the pharmacists.[34,35] Patients were familiar with the basic information only such as the dose, frequency, and duration ignoring the essential beneficial knowledge related to the treatment safety, efficacy, and monitoring.[36]

Pharmacists in chain pharmacies were more likely to ask about the patient`s performance of the required laboratory tests (p=0.001) and more likely to advise about the importance of using sun protection before sunlight exposure as estimated using the chi-square test (mean = 127, p= 0.021). An increase in the internal quality, comprehensive logistics, continuous pharmacists training, and implementing new patient`s oriented services were probably making the chain pharmacies superior to independent pharmacies.[37] The mutual business interests of the chain pharmacies with

medical clinics and pharmaceutical companies may justify the reported results as pharmacists may recommend laboratory tests in specific clinics and advise the patients to use sunprotection from a specific pharmaceutical company.[38]

The overall pharmacists' counseling that was assessed by this study was "incomplete". Only 1.5% of the pharmacists advised the SP about the possible ADRs. Also, only 31% of the pharmacists advised the SP to have laboratory tests for monitoring. Only 5% of the pharmacists counseled about the need of using contraceptive while receiving the isotretinoin. About 62% of the pharmacists counseled the SP properly about the importance of treatment compliance. An interventional study revealed that professional pharmacists' leads to a significant reduction in the mean number of patient`s drug-related problems (DRPs) after four months of intervention (mean difference 16%).[39] The study found that pharmacists are in a better position to influence patients or physician attitude, behavior, and level of knowledge regarding the ADRs, through counseling as another study finding.[35] Pharmacist counseling improves medication adherence that minimizes adverse drug reactions.[40] This was estimated through observational and interventional periods conducted using 1844 patients. The number of patients adherent to the treatment regimen increased from 51% to 67% ($p<0.01$). The percent of unfilled medications decreased from 50% to 33%. In Croatia, the reported percent of patient's adherence increased slightly by 4% when patients were interviewed at first and next visit.[41] Pharmacists assumed that patients knew everything related to dispensed medicines. This resulted in a low chance of communication between pharmacists and patients which led the patients to be less interested in medication adherence. In Europe, pregnant women were still exposed to isotretinoin therapy. These were attributed to the poor level of community pharmacist implementation of the isotretinoin pregnancy prevention program.[42] A study found that only 6% of the community pharmacists advised patients about using contraception and 11% of them did not check whether the patients performing the required pregnancy tests.[29] Moreover, another study reported that 15% of patients were asked about the negative pregnancy test and 49% of the pharmacists checked whether the contraception was in use.[43] Furthermore, a cohort study among women of reproductive age found that the concomitant use of hormonal contraceptives with isotretinoin therapy was only 59%.[44] If the pharmacists find that the female patients are not getting enough protection by using contraceptives or undergoing the required pregnancy test, he/she should not dispense the isotretinoin capsules. The pharmacists have to counsel and refer the patients to a specialized physician to prescribe the most suitable contraceptives and undergo the pregnancy tests before getting the isotretinoin capsules. Recently, it was shown that pregnancies, abortion, and fetal birth defects were decreasing since the implementation of a restricting program and encouraging pharmacist`s intervention.[14]

The different observations that we reported previously imply the differences in countries in many aspects such as pharmacy dispensing system, pharmacist`s training, and education, regulations, and the implemented protocols that regulate health care professionals' practice.[45] In the USA and Europe, several stages were implemented to minimize the exposure to isotretinoin during pregnancy. Initially, the pregnancy prevention program (PPP) provided health care providers with a set of educational materials. However, various studies revealed the poor compliance of the community pharmacists with the program regulations.[42–44,46,47] After applying iPLEDGE regulations, patients' access to isotretinoin therapy became more restricted by limiting the isotretinoin prescription from general practitioners to specialist providers.[12] Community pharmacists demonstrated a low level of adherence to the system requirements in a multicenter retrospective study.[48] This is because multiple steps must be completed within restricted time to prescribe/dispense isotretinoin capsules, these resulted in the interruption or discontinuation of the therapy course.[49] Unlike in the USA and Europe, a controlled medication E-prescription platform called Open Jet system that was implemented in UAE included some regulations that restricted the patients' information, prescription date, generic/brand name, dose, frequency, and duration of the medicine only.[19] It did not include requirements that needed for the prescriber or dispenser to be followed for the proper patient's assessment such as laboratory tests, pregnancy status, contraindications, or interactions.

Several reasons were used to explain our findings; the traditions and culture in UAE had an impact on the pharmacist's attitude especially when a male pharmacist tends to assess a female patient for their pregnancy status and when he counseled the patient about the pregnancy test because these are considered private and sensitive issues for the population in UAE. Our study showed that female pharmacists were assessing the SP`s pregnancy status significantly more than male pharmacists (female=134, male=77, $p=0.001$). In addition, female pharmacists were

more likely to provide counseling about the pregnancy test (mean=134, p=0.001). Proper counseling service provided by the community pharmacist was dramatically impacted because of the absence of a designated consultation area as it was observed in most of the visited pharmacies which limit the privacy of the patient. Some patients may feel uncomfortable if the pharmacists asked questions or tried to provide them with additional information about the requested medicine.[50] Another possible reason is that a limited number of pharmacists working with workload adversely affecting the patient-related services as a result of time constraints.[36,51] The type of the medicines prescribed and patient-criteria decided the quality of the counseling provided to patients.[52]

Insufficient education and training of the pharmacists before graduation and post-graduation had a great impact. In the USA, the Accreditation Council for Pharmacy Education (ACPE) mandates that the graduates of pharmacy programs be well educated and trained to be competent in providing pharmaceutical care.[53] In UAE, there are no protocols implemented by the ministry of health or other pharmaceutical organizations that mandates for patient`s assessment for the effective and safe use of controlled/semi-controlled medicines. This is the case for isotretinoin which is known as strong teratogenic medicine. The health authorities require an internship from pharmacy program graduates for six months only to get the practice license after passing a licensing exam. This internship must be structured, effective, emphasizing specific learning objectives and supervised by the pharmacist's in-charge. Continuous and up to date medication education for pharmacy professionals is required.[54] For example in India, when a structured continuous professional development program (CPD) was implemented a significant improvement ($p<0.05$) was demonstrated in medication counseling.[55] Moreover, continuing education revealed a great improvement in pharmacist`s knowledge, attitude, and patient counseling.[56]

Study Limitations

In our study, all the pharmacies were visited by only one SP. According to one article, the data collected by using only one SP makes the results more limited and less generalizable than other studies that used more than two SP for data collection. On the other hand, Inter-rater variability is minimized in this study because only one SP was involved which will make the data collection process more consistent. This also agrees with another study in UAE using one SP.[55] The involvement of several SPs makes the standardization of the results more challenging.[57] In addition, the researcher did not revisit the pharmacy to give the pharmacist information on the ideal scenario to handle such a semi-controlled drug.

Conclusion

This study showed that inadequate assessment, counseling, and advice-giving were provided by the community pharmacists to the SP toward isotretinoin prescriptions. Suboptimal level of patient`s assessment was demonstrated by our study with an inconsistent collection of essential data required for the determination of patient`s eligibility for safe and effective use, as well as poor educational counseling regarding the isotretinoin capsules. New strategies are needed to improve the pharmaceutical care services among community pharmacies in UAE to monitor and optimize medicines use especially medicines that are associated with serious health risks such as isotretinoin. Community pharmacists need additional education and training in the area of oral isotretinoin. Emphasis should be considered on educating the pharmacists on how to evaluate the safety, efficacy, and patient's eligibility to use the isotretinoin especially for female patients in childbearing age. The results of this study will be critical to pharmacy educators and regulators worldwide who are responsible for implementing and developing professional practice standards for community pharmacists regarding oral isotretinoin. Besides, these findings are critical to the dermatologists who prescribe the oral isotretinoin and primarily responsible for the patient`s safety.

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Author contributions

All authors contributed to data analysis, drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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