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Original Research

Evaluating the practice of Iranian community pharmacists regarding oral contraceptive pills using simulated patients

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ABSTRACT

Background: As oral contraceptive pills are available over the counter in pharmacies, pharmacists are professionally responsible for checking and informing patients about every aspect of taking these drugs. Simulated patient method is a new and robust way to evaluate professional performance of pharmacists.

Objective: The aim of the present study was to evaluate the pharmacy practice of Iranian pharmacists regarding over-the-counter use of oral contraceptive pills using simulated patient method.

Methods: Simulated patients visited pharmacy with a prescription containing ciprofloxacin and asked for oral contraceptive pills. The pharmacist was expected to ask important questions for using these drugs and to inform the patient about them properly. Moreover, the Pharmacists should advise patients in regard to the possible interaction.

Results: Ninety four pharmacists participated in this study. In 24 (25.3%) visits, the liable pharmacist was not present at the time of purchase. Furthermore, In 13 (18.57 %) visits by the simulated patients, the liable pharmacists did not pay any attention to the simulated patients even when they asked for consultation. Twenty nine (41.43%) pharmacists did not ask any question during dispensing. Nausea was the most frequent described side effect by pharmacists (27 (38.57%)). Yet important adverse effects of oral contraceptive pills were not mentioned by the pharmacists except for few ones. Only twelve (17.14%) pharmacists mentioned the possible interaction. There was a significant relation between the pharmacists' gender and detection of possible interaction (p value= 0.048).

Conclusion: The quality of the pharmacists' consultations regarding the over the counter use of oral contraceptive pills was not satisfactory and required improvement.

Keywords: Contraception; Postcoital; Pharmacies; Community Pharmacy Services; Professional Practice; Patient Simulation; Iran

INTRODUCTION

Oral contraceptive pills (OCPs) are among the most frequent methods of birth control in different countries. Most of OCPs consist of estrogen and progesterone components. These pills can achieve more than 99% success in their main indication by correct use.¹

OCPs can cause some side effects such as breast pain, tenderness, heavy non-menstrual vaginal bleeding, severe headache, irregular menstrual periods and nausea. Also these pills have some contraindications and warnings for women who suffer from cardiovascular diseases, high blood pressure, thromboembolic events, significant liver disease, systemic lupus erythematosus, migraine with aura, etc. and for those who smoke and are over 35 years of age.^{2,3} Some studies in the United States have demonstrated 16-39% of women in reproductive age have at least one contraindication for using OCPs. Therefore, health professionals should perform a screening that includes medical and family history of patients, and blood pressure checking for OCPs users.^{4,5}

In some countries, OCPs are only available by a physician's prescription, so the use of OCPs is restricted.⁶⁻⁸ On the other hand, in some countries, OCPs are available as over-the-counter (OTC); thus it is necessary for women to have adequate knowledge about these drugs.⁹ However, the priority of each of the above is controversial.³ Generally, because of the fact that pharmacists are the last health professionals that patients meet, they have a vital role in educating the patients. Pharmacists must assure that OCPs users have enough information about OCPs especially in OTC access⁹, but this responsibility of pharmacists has not been taken perfectly in some countries. Some studies reported that the quality of pharmacists' consultations regarding the use of OCPs was not good enough and required improvement.^{3,10}

Considering the above, it seems necessary to assess the counselling skills of community pharmacists. In this respect, simulated patient method is a new and robust way to evaluate professional performance of pharmacists.¹¹ Simulated patient (SP) is an individual who is appointed to visit a pharmacy with a special scenario which is designed by scholars to assess the particular behavior of a pharmacist or pharmacy personnel. In this method pharmacists do not know that they are under assessment.¹² Recently, there has been a growing interest in using this method¹³ which does not have the methodological limitations

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(like overestimation of the quality of pharmacy practice) of quantitative methods such as self-reported questionnaires and interviews.³

Since OCPs are frequently used for contraception in Iran¹⁴ and these drugs are delivered OTC, women need to be informed about the proper use of them. As OCPs are available OTC in pharmacies, pharmacists are professionally responsible for checking and informing patients about every aspect of taking these drugs. However, there is limited research examining dispensing practice of pharmacists with regard to OCPs in Iran. Also, the simulated patient method has been rarely implemented to evaluate pharmacy practice of community pharmacists regarding OCPs in Iran. The aim of the current study was to evaluate the pharmacy practice of Iranian pharmacists regarding OTC use of OCPs using simulated patient method.

METHODS

The current study was performed in Kerman, a city located in the south east of Iran during October 2015. The study protocol was approved by the ethical committee of Kerman Medical University. There were approximately one hundred community pharmacies in Kerman. One or two months before the SPs went to pharmacies, the managers of the pharmacies had been informed by the researchers that an SP would come to their pharmacies in the following days and oral consent had been obtained. Some characteristics of the pharmacists including age, sex, weekly working hours, duration of work as a pharmacist and ownership of the pharmacy were recorded according to Food and Drug Organization of Kerman.

Three young girls, about 30 years old, were selected as SPs. They were notified about simulated patient method and trained for communicating techniques and evaluated by the researchers to play the scenario satisfactorily. Training SPs took approximately 8 hours. Each community pharmacy was visited once by only one of the three SPs. The SPs did not give any information to pharmacist unless they were asked. The SPs were also chosen in a way that none of the pharmacists could detect them. If they were recognized, the scenario would not be played in that pharmacy at that time, and another SP was chosen to be sent to that pharmacy in another time. In all the cases, the SPs left pharmacies after playing the scenario without being identified as a simulated patient by pharmacists. Date and time, number of clients presented in the pharmacies and name of the liable pharmacists were recorded by the SPs.

The following scenario was used in this study. A 30-year old woman recently married visited a pharmacy with a prescription containing 10 ciprofloxacin 500mg tablets. She had not used any hormonal method for contraception and asked for OCPs. Her menstrual cycle was regular and normal. She was suffering from diarrhea for three days; hence a physician had prescribed an antibiotic for her. Also, she did not use any other drugs and did not smoke.

There was not anything special in her family history and she had no contraindication for use of OCPs.

It is notable to say that the use of OCPs and antibiotics simultaneously is a challenging issue because of the possible risks of contraceptive failure.^{15,16} Rifampin is the first antibiotic whose interaction with OCPs was proven. Rifampin is a potent inducer of cytochrome P-450 and reduces the level of estrogen and progesterone. Several mechanisms are proposed for this interaction between antibiotics and OCPs such as inducing cytochrome P-450, causing diarrhea and vomiting, and interrupting the enterohepatic circulation of estrogen caused by altering intestinal flora.¹⁷ According to the Centers for Disease Control and Prevention, there is no limitation for the simultaneous use of OCPs and broad spectrum antibiotics such as metronidazole, ampicillin, ciprofloxacin, and tetracycline due to the lack of sufficient clinical evidence. In practice, one approach recommended by some experts is that if there is another factor reducing OCPs effectiveness such as vomiting or diarrhea, backup method should be used. Another approach which is conservative is to use backup contraception while taking antibiotics because the possibility of birth control failure cannot be excluded. In the above mentioned approaches, the backup method is used during antibiotic consumption and for at least one week after discontinuation of antibiotic.^{17,18}

The authors of the present study expected the pharmacists to evaluate family history, medical history and contraindication conditions of OCPs users. They were also expected to explain the side effects of OCPs and the ways for managing them. Moreover, the Pharmacists should advise patients in regard to the possible interaction (particularly for this case because the SP had one factor that reduced OCPs effectiveness) and should mention the use of alternative methods during ciprofloxacin use and for at least one week after discontinuation of ciprofloxacin. The joint International Pharmaceutical Federation (FIP)/World Health Organization (WHO) guidelines on Good Pharmacy Practice¹⁹ was used in our study to determine the responsibilities of and expectations from pharmacists.

This scenario was chosen due to high prevalence of such a case in society. A physician accepted to write the needed prescription for the research. After the entering of the SP into a pharmacy, if the pharmacist did not counsel her, she would ask for a consultation with the pharmacist. During the consultation, the voice was recorded and after that one of the researchers listened to it and filled out the questionnaire. The questionnaire included items that were to be asked or explained by the pharmacist such as age, smoking, side effects and the ways for managing them, marital status, breast feeding, blood pressure, drug history, family history, menstrual cycle regularity, reasons for using these pills, abnormal vaginal bleeding, contraindications, possible drug interaction, and recommendation for alternative methods.

Characteristics	Number of pharmacists n (%)	Impact on detection of the potential interaction (p-value*)
Age		0.337
- Less than 30 years	32 (34.0%)	
- 30-50 years	48 (51.1%)	
- More than 50 years	14 (14.9%)	
Sex		0.480
- Male	64 (68.1%)	
- Female	30 (31.9%)	
Weekly working hours		0.970
- Less than 30 hours	9 (9.6%)	
- 30-60 hours	47 (50.0%)	
- More than 60 hours	38 (40.4%)	
Duration of work as a pharmacist		0.760
- Less than 2 years	24 (25.5%)	
- 2-10 years	32 (34.0%)	
- More than 10 years	38 (40.4%)	
Ownership of the pharmacy		0.698
- Yes	64 (68.1%)	
- No	30 (31.9%)	

*Based on chi-square test or Fisher's exact test

The statistical package of social science (SPSS) version 20 was used for all the analyses. Descriptive analysis was used for all the variables, and chi-square (or Fisher's exact test) was used to determine the relationship between the qualitative variables. The p-value less than 0.05 was considered as statistically significant.

RESULTS

Among 96 active community pharmacies, 94 managers of the pharmacies accepted to participate in this study. In general, consultations were brief and their duration ranged from 1 to 22 minutes. In 24 (25.3%) visits, the liable pharmacists were not present at the time of purchase in spite of the fact that the SPs waited for the pharmacists more than 30 minutes. Furthermore, in 13 (18.57 %) visits by the SPs, the liable pharmacists did not pay any attention to the SPs even when they asked for consultation. Three of these 13 pharmacists asked their staff to answer the SPs' questions. Eleven (15.71%) pharmacists counseled the SPs upon requesting. And in 3 (3.19%) pharmacies, the patient's privacy was protected and two of them had

consultation area. Also one (1.43%) of the 70 present pharmacists used jargon in his consultation. In 57 (60.6%) visits, the number of clients in the pharmacy during the SP visit was less than or equal to three people. Some characteristics of the liable pharmacists who participated in this study and their impact on detection of the possible interaction are shown in Table 1.

In addition, every participated pharmacist asked 1.5 questions on average. Female pharmacists asked more questions than male pharmacists (2.34 versus 1, on average). Twenty nine (41.43%) pharmacists did not ask any questions during dispensing. None of the pharmacists asked questions about blood pressure or drug history of the patient during dispensing. Also nine (12.86%) pharmacists asked the patients the reason of using OCP. Moreover, twenty five (33.33%) pharmacists asked questions about the patients' financial affordability.

Nausea was the most frequent described side effect by pharmacists (27 (38.57%)). Yet important adverse effects of OCPs were not mentioned by the pharmacists except for few ones like weight gain (5 (7.14%)), acne (4 (5.71%)), cardiovascular side effects (2 (2.86%)), melasma (2 (2.86%)), and

	Pharmacists covering the topic, n (%)	Relation with detection of the potential interaction (p-value*)
Questions expected to be asked		
Age	3 (4.29%)	0.004
Cigarette smoking	3 (4.29%)	0.004
The number of cigarettes smoked per day	0 (0%)	-
Marital status	6 (8.57%)	0.058
Previous method	5 (7.14%)	0.201
Breastfeeding	1 (1.43%)	0.892
Regular menstrual cycle	1 (1.43%)	0.892
Abnormal vaginal bleeding	1 (1.43%)	0.892
Family history	2 (2.86%)	0.892
Contraindications	7 (10%)	0.014
Advice expected to be given by the pharmacists		
Adverse effects	33 (47.14%)	0.034
Ways for managing adverse effects	2 (2.86%)	0.684
Instructions on how to use	16 (22.86%)	0.517
Interaction	12 (17.14%)	-
Alternative method because of interaction	5 (7.14%)	0.002

*Based on chi-square test or Fisher's exact test

depression (3 (4.29%)). Also 21 (30%) pharmacists declared there were not any side effects caused by these drugs. Sixteen (22.86%) pharmacists provided instructions on how to use OCPs. Only few Pharmacists explained the possible interaction and recommended the alternative methods. Table 2 presents the questions or advices expected to be asked or given by the 70 present pharmacists and their relation with detection of the possible interaction. Asking about age, cigarette smoking and contraindications, and provision of advice concerning adverse effects and alternative methods because of the interaction had significant relation with the detection of the possible interaction.

There was a significant relation between the pharmacists' gender and detection of the possible interaction ($p=0.048$). The female pharmacists detected the interaction more than male pharmacists. Also, no significant relation was found between detecting the possible interaction and other pharmacist related factors including age, weekly working hours, duration of work as a pharmacist, and ownership of the pharmacy. Moreover, the number of clients in a pharmacy during SPs' visits did not have any significant effect on detection of the possible interaction ($p=0.116$).

DISCUSSION

In the present study, the reliable pharmacists (25.3%) were not physically present in pharmacy during working hours. This fact was reported previously.²⁰ This situation made the non-pharmacist pharmacy staff provided OCPs; thus having adequate knowledge in this regard was necessary for the staff. Similarly in Nigeria, researchers evaluated the screening practice of pharmacy staff. It was concluded that pharmacy staff did not have enough information about contraindications of OCPs. Therefore training pharmacy staff was suggested.²¹ Although It has been reported that higher prescription volume and Pharmacists' workload had significant effect on detection and prevention of drug-related problems like drug-drug interactions²², in the current study, the number of clients in a pharmacy, causing workload, during the SP visit did not have any significant effect on detecting the possible interaction. In the present study, only one of the participated pharmacists used jargon in his consultation. Avoiding jargons and speaking clearly are reasonable, because they make communication more understandable for patients.^{23,24} In addition, lack of patients' privacy was apparent in the current study, and it might be a barrier to give patient counseling.²⁵

The present study demonstrated that pharmacists should devote more attention to OTC use of OCPs. According to the results of this study, up to 3% of the pharmacists inquired medical history before selling OCPs, 10% asked about contraindications, more than 40% did not provide any counselling and more than 95% ignored the OCPs users' age. All these indicated the provision of poor counseling on OCPs by the pharmacists. Moreover, less than 18% of the pharmacists mentioned the possible

interaction, less than 8% recommended backup method and no one asked about diarrhea. This might be due to the knowledge deficiency of the pharmacists or their reluctance to apply their knowledge. It should be noted different types of scenarios might affect the rate of information gathering and also provision of appropriate advice, because the level of knowledge of pharmacy staff regarding different scenarios might be different.^{20,26}

However, the results of the related studies were different in other countries. The possible reasons for this fact were differences in countries regarding pace of development, health care systems, pharmacy education systems, and pharmacy staff training.²⁰ In addition, this difference revealed that pharmacy practice in low- and middle-income countries like Iran is very poor in comparison with high income countries. Some reasons for this low quality of pharmacy practice seems to be lack of trained and competent pharmacists, low remuneration for pharmacists, lack of proper control, and unrecognition of the importance of pharmacists' role within health care systems.²⁷⁻²⁹

The results of the following studies confirm the above mentioned facts. A cross sectional study assessed the quality of consultation in regard to contraceptive pills among 41 community pharmacists using simulated patient method in Brazil on June-October 2012. The results of the mentioned study revealed that these pills were dispensed inappropriately and consequently caused adverse effects and contraceptive failure. In the scenario of this study, SPs took carbamazepine which may decrease the efficacy of OCPs. None of the pharmacists mentioned this important interaction. And only one out of 41 pharmacists asked about the age of OCPs users.³ In another study undertaken in Australia, in 2008, the provision of emergency contraceptive pills by pharmacy services were evaluated in a five week study among 100 pharmacies using the simulated patient method. Guidance was adequate in 49% of the consultations and insufficient in 3% of them. It was reported that the quality of the consultations was good but needed more efforts to improve it.¹⁰ Furthermore, Schneider et al investigated the effects of using a written assessment checklist by pharmacists on provision of emergency contraceptive pills in a simulated patient study in 2013. They concluded using the checklist increased the number of assessment questions but did not improve the appropriate outcome in regard to medication supply.³⁰ Also, in United Kingdom, the clinical and communication skills of 40 pharmacists regarding emergency hormonal contraception (EHC) supply were investigated. There, the SPs played two scenarios. In the first one, the supply of EHC was appropriate and overall the quality of the pharmacists' consultations was good. In the second one, there was an interaction between EHC and St John's Wort (It was in SPs drug history) and 89% of the participated pharmacists detected the interaction. The results of this study revealed the quality of communication skills was high.²⁴

Our results also demonstrated that the gender of liable pharmacists had a significant effect on detecting the possible interaction. Also the female pharmacists asked more questions than male pharmacists during dispensing OCPs. On the contrary, the results of a similar study using SPs showed that gender did not have any effect on the quality of counselling regarding OCPs use, but it indicated that the female pharmacists were more empathic, and it made patients more comfortable.¹⁰ In another study undertaken in Iran using standard patient, it was revealed that pharmacists had limited and unsatisfactory knowledge about emergency contraception. It was stated that the female pharmacists had significantly more knowledge regarding emergency contraception method than male pharmacists.³¹ Moreover, another study carried out in Iran using a questionnaire about OCPs use showed that the knowledge of pharmacists about OCPs was not at the expected level, and in some areas they provided incorrect information. Deficiencies in communication skills also were apparent.³² The last two mentioned studies undertaken in Iran confirmed the results of the present study.

Previous studies showed that the OTC availability of OCPs is more desirable for women^{3,9,33} because it could be more convenient and more cost effective, could reduce unintended pregnancies, and could improve OCPs continuation.^{8,34} The researchers of the present study believe that it can be rational to sell OCPs as OTC drugs, but the counselling practice of community pharmacists must be improved. Since community pharmacists did not provide adequate counseling for OCPs users, women preferred to read information leaflet. According to a survey in England, providing leaflet and offering it to OCPs users could increase knowledge of such users and prevent unwanted pregnancies or some side effects.³⁵ In addition, as it was surveyed in a study in the United States, increasing OCPs users' information would lead women to use these pills correctly without provision of counseling.³⁶ It was also noted that sometimes giving additional information to patients caused negative reactions.³

With due consideration of the above, some efforts are needed to improve pharmacy practice of pharmacists. One of the efforts made in this regard can be the offering of clinical and experimental courses in pharmacy undergraduate level particularly in Iran because the ability of pharmacy

graduates in Iran as drug consultants has not been at the expected level.³⁷ Another effort, reported by James et al, should be the structured teaching program using SPs which can improve the counselling skills of undergraduate pharmacy students.³⁸ SPs can be also used to assess the pharmacy practice of community pharmacists.¹³ Of the other efforts made in this respect can be learning activities such as using standardized patients, interdisciplinary methods, and using Internet or computer technology, and holding seminars for pharmacy students.³⁹ Finally, designing guidelines or checklists in regard to OTC use of OCPs to determine which types of questions should be asked by pharmacists could be helpful.^{20,30} The irrelevant types or inadequate information gathered by pharmacists might lead to provision of inappropriate advice.^{20,26}

The current study was conducted in one of the cities of Iran, but similar studies should be performed in other cities of Iran (because of differences in socio-economic status and health care resources 26) to reach definite conclusions.

CONCLUSIONS

It was concluded that the pharmacy practice of pharmacists regarding OTC use of OCPs were far from satisfactory level. Accordingly screening OCPs users for contraindications and informing them about the adverse effects are pharmacists' duties and they should take more responsibility for OCPs users.

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CONFLICT OF INTEREST

The Authors declared that there is no conflict of interest.

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