

Evaluation of Community Pharmacists Knowledge, Attitude and Practice towards Modified Release Dosage Forms (Conference Paper)

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9th scientific conference sponsored by College of Pharmacy, University of Baghdad 25-26 August 2021

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Abstract

To evaluate knowledge, practice and attitude of community pharmacists in Basra regarding modified release dosage forms which are widely used for many therapeutic purposes in pharmacy practice.

The current study was conducted among certified pharmacists in Basra governorate- south of Iraq. Data collection was carried out by a self-developed questionnaire in a cross-sectional study.

A total number of 175 community pharmacists responded to the questionnaire. The majority worked in over the counter drugs based dispensing pharmacies located in the center of the city. Only 38% of respondents correctly answered the first question in the knowledge section. There was a major positive agreement (75 %) towards medical representatives' rule in promoting the prescribing of modified release products by physicians. Avoiding crushing and breaking of solid oral modified release drugs were identified by the majority (70%) of participants. Correlation analysis showed a 22.8 correlation coefficient between knowledge and practice which was statistically significant. There was a statistically significant higher knowledge and practice scores in males than females.

The result of this study demonstrates the lack of knowledge in many aspects regarding modified release dosage forms with several negative attitudes towards and practicing errors regarding modified release dosage forms. The conduction of a brief educational program would be very beneficial in bringing basic theoretical knowledge with practicing points of interest and promote a more positive attitude toward this unique class of novel drug delivery system.

Keywords: Modified release products, Community pharmacists, Knowledge, Attitude, Practice, Basra.

تقييم معرفة الصيادلة المجتمعيين، الموقف والممارسة تجاه نماذج الجرعات مُعدّلة التحرّر (بحث مؤتمري)

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الخلاصة

تقييم معرفة، ممارسة وموقف صيادلة المجتمع في البصرة فيما يتعلق بأشكال الجرعات مُعدّلة التحرّر المستخدمة بصورة واسعة للعديد من الأغراض العلاجية في ممارسة الصيدلة. أجريت الدراسة الحالية على الصيادلة المعتمدين في محافظة البصرة جنوب العراق. تم جمع البيانات من خلال استبيان. استجاب للاستبيان ١٧٥ صيدلياً من المجتمع المحلي. غالبية المستجيبين يعمل في صيدليات تقع في مركز المدينة وتعتمد نظام صرف الأدوية التي لا تحتاج لوصفة طبية. تمكن فقط ٣٨٪ من المستجيبين عن الاجابة بصورة صحيحة عن السؤال الأول في قسم المعرفة. كان هناك اتفاق إيجابي كبير تجاه قاعدة المسؤولية الطبيين (٧٥٪) في تعزيز وصف المنتجات المعدلة من قبل الطبيب. تم تحديد تجنب سحق وكسر الأدوية الصلبة المعدلة عن طريق الفم من قبل غالبية المشاركين (٧٠٪). أظهر تحليل الارتباط أن معامل ارتباط ٢٢,٨ بين المعرفة والموقف كان ذا دلالة إحصائية. أظهر الذكور درجات معرفة وممارسة ذات دلالة إحصائية أعلى من الإناث.

تظهر نتيجة هذه الدراسة نقص المعرفة في العديد من الجوانب المتعلقة بأشكال الجرعات مُعدّلة التحرّر مع العديد من المواقف السلبية وممارسة الأخطاء فيما يتعلق بأشكال جرعة الإطلاق المعدلة. إن إجراء برنامج تعليمي موجز سيكون مفيداً جداً في جلب المعرفة النظرية الأساسية مع ممارسة نقاط الاهتمام وتعزيز موقف أكثر إيجابية تجاه هذه الفئة الفريدة من نظام توصيل الأدوية الجديد. الكلمات المفتاحية: الجرعات مُعدّلة التحرّر، صيادلة المجتمع، المعرفة، الموقف، الممارسة، البصرة.

Introduction

Modified release dosage forms can be defined as drug products that alter the timing and/or the release pattern of the active drug substance ⁽¹⁾. They come into different classes including extended

release, delayed release, repeated action and targeted release dosage forms ⁽²⁾. Extended release can be further classified into controlled and sustained depending on the rate of release whether it is predetermined or not respectively ⁽³⁾.

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Received: 27/8/2021

Accepted: 15/11 /2021

Published Online First: 2022-1-12

Modified-release release dosage forms can provide several benefits. Firstly, the reduction in dosing frequency and fluctuation in circulating drug concentration⁽⁴⁾.

Secondly, increasing patient compliance and decreasing dosing frequency⁽⁵⁾. Finally, enhancing overall drug bioavailability and pharmacokinetic properties⁽⁶⁾. However, it also has disadvantages summarized mainly in dose dumping and low potential for dosage adjustment and higher cost compared to conventional dosage forms⁽⁷⁾.

The knowledge, attitude and practice (KAP) survey can collect quantitative and qualitative information depending on specific questions formatted in standardized questionnaires. It is mostly used as a tool to address misconceptions or misunderstandings that might be an obstacle towards the implementation of a certain behavior change⁽⁸⁾.

Over the years, several drugs were marketed as modified products and proved their success in therapy. Nevertheless, KAP insufficiency among healthcare professionals was noticed.

As the core pharmaceutical services represented by promoting the correct and safe use of medications⁽⁹⁾. Therefore, pharmacists were selected as a target for this research. Once the level of participants is determined, it would be defined as a quantitative method that is used to be easier to detect what elements are mostly deficient and suitable interventions will be directed towards the defect. It is expected that educational intervention will provide this goal as it was helpful in similar areas⁽¹⁰⁾.

Previous study in Benghazi was conducted to evaluate the knowledge and perception of pharmacy practitioners toward sustained release dosage forms. The study showed that most patients and physicians lack knowledge about the advantages and disadvantages of these dosage forms which can discourage use. Also, it is the pharmacy practitioner duty to enhance their understanding and promote the full benefit of using these dosage forms⁽¹¹⁾. Another study at Khartoum locality revealed that community pharmacists have a moderate knowledge with a general negative attitude and an acceptable practice regarding these drugs with different delivery patterns⁽¹²⁾.

The aim of the present investigation is to address the knowledge, attitude and practice of community pharmacists in Basra regarding the modified release dosage forms. The required information is obtained by a pre-validated questionnaire and the data collected were evaluated by different descriptive and inferential statistical tools.

Methods

Questionnaire

The knowledge, practice and attitude of community pharmacists were assessed by a self-developed questionnaire in a cross-sectional study. The

questionnaire was approved by the Scientific Committee in the Clinical pharmacy, College of Pharmacy, Basra University. The test-retest method was used to evaluate the reliability of the questionnaire. This is done by carrying out a pilot study on thirty participants. Ten days later, the same participants were asked to re-fill the questionnaire. The first section, knowledge, consisted of 6 questions. Each of the second and third sections consisted of four questions related to attitude and practice respectively.

Each correct answer in the knowledge and practice section was marked with 1 while wrong or don't know answers carried 0 marks. This gave a total score in the range of 0 – 6 for the knowledge section and from 0 to 4 in the practice section. In the attitude section, positive attitude with agreement was marked with 3, neutral carried 2 marks while negative attitude with disagreement were given 1 according to Likert scale^(13, 14). This gave a score range from (1- 3) for the attitude section. The reliability of the questionnaire data was evaluated using Cronbach alpha coefficient⁽¹⁵⁾.

Study design

This study was an observational cross-sectional, pharmacists in Basra governorate were provided with questionnaires by a researcher. Data collection was carried out through the period from 12th of January to 15th March in 2020. The purpose of the study was illustrated briefly to the pharmacists, then they were requested to fill in the questionnaire. The questionnaires were either collected by the researcher or returned by the participants themselves after half an hour.

Statistical analysis

Data analysis was carried out by the SPSS program, version 17.0. The demographic data were coded and the answers were marked according to each section's requirements. The demographic data of the participants and their responses were described by descriptive statistics in terms of frequency and percentages. For determining the appropriate inferential statistical test, the responses in the three domains of the questionnaire were tested for normality using Kolmogorov-Smirnov test. As the normality condition was not achieved, non-parametric tests, Mann-Whitney for two U tests and Kruskal Wallis H test for more than 2, were used for analyzing the significance of each demographic characteristic on each domain in the questionnaire. For each test, a p-value of less than 0.05 was considered statistically significant.

Results

The reliability of the questionnaire was confirmed since there was no significant difference between the pilot studies earlier performed. There were 175 responses from participants to the questionnaire. The demographic data of the questionnaire participants are shown in Table (1). The Cronbach Alpha coefficient was used where its

value was (0.67). This ensures the ability of the study tool to measure the dimensions and prove their validity and reliability.

It was found that the majority of participants around 72.57% belonged to the age (24-35) years and only 4% had age 46 years and over. The number of females that participated in the questionnaire was higher than males which were 57.71% and 42.28% respectively. Regarding the qualification of participants, about 77.14% had B.Sc. in pharmacy and just 2.85% had a specialty in pharmaceutical science. Approximately half of the participants had 1-5 years of practice in community pharmacy. The percentage of pharmacists that had (1-5) years after graduation was approximately equal to the percentage that had more than 10 years from graduation which was 33.14% and 34.28% respectively. Concerning the location of pharmacies, high percent of pharmacies around 78.28% located in the center of Basra city and the majority of the pharmacies (66.85%) were dependent on over the counter (OTC) mode of dispensing, i.e., the drugs were dispensed by the pharmacists.

Knowledge about modified release dosage forms

Pharmacists' knowledge about modified release dosage forms was evaluated by using six questions relating the basic theoretical background and practical evidence from marketed dosage forms as shown in Table 2. Less than half of participants answered the first and the third question in the knowledge section correctly. The majority of participants were unable to distinguish the different categories of modified release products by symbols printed on their packaging. Also, the risk of dose dumping is higher with modified products than immediate as they mostly contain more drugs so dosage failure is more serious. On the other hand, more than three-quarters (78% and 94 %) of participants realized the benefit obtained from these dosage forms by increasing drug bioavailability and decreasing adverse drug reactions and increasing patient compliance, respectively. In addition, a high percentage of participants (68%) were aware that not

all drugs could be formulated as modified release formulations. Moreover, a large proportion of participants (71%) considered modified release formulations to be more sophisticated dosage forms and require more complicated preparation steps if compared with immediate release formulations.

Table 1. The demographic data for all participants

Demographic characteristic	
Frequency n (%)	
Age	
24-35 years	127 (72.57)
36-45 years	41 (23.42)
46 years and over	7 (4)
Gender	
Female	101(57.71)
Male	74(42.28)
Qualification	
BSc Pharmacy	135 (77.14)
Pharmaceutics Specialist	5 (2.85)
MSc in pharmacy	24 (13.71)
PhD in pharmacy	11 (6.28)
Years in community pharmacy Practice	
less than 1 year	31 (17.71)
1-5 years	78 (44.57)
6-10 years	31 (17.71)
more than 10 years	35 (20)
Years from graduation	
less than 1 year	16 (9.142)
1-5 years	58 (33.142)
6-10 years	41 (23.42)
more than 10 years	60 (34.28)
Pharmacy location	
Center of the city	137(78.28)
Countryside	38(21.71)
Mode of Dispensing in the pharmacy	
OTC by the Pharmacist	117 (66.85)
By Prescription	58 (33.142)

Data presented as number and percentage, n = 175

Table 2. Frequency of responses to questions in knowledge section

	Question	Yes (n %)	No (n %)	I do not Know (n %)
K1	The terms, controlled release –extended release – delayed release and Zero Order Kinetic are interchangeable	94 (54)	66 (38*)	15 (9)
K2	Modified release formulations increase drug bioavailability and decrease adverse drug reactions	136 (78 *)	28 (16)	11 (6)
K3	Modified release formulations cause more side effects than immediate release formulation if inappropriately formulated.	60(34*)	83 (47)	32 (18)
K4	Reduction of the dosing frequency results in enhancement in patient compliance and therapeutic outcomes when using modified release formulations.	164(94 *)	5(3)	6 (3)
K5	All Drugs can be formulated as Modified release formulations, they are considered good candidate with good therapeutic outcomes	32(18)	119 (68*)	24 (14)
K6	Modified release formulations are more sophisticated dosage forms in comparison with immediate release formulation and involve more complicated preparation steps.	125(71*)	11 (6)	39 (22)

Data presented as number and percentage, n = 175

*Correct answer

Attitudes towards modified release dosage forms

To investigate the attitudes of pharmacists towards controlled release dosage forms, four questions were designed. Their responses were described in Table (3). Approximately half of participants had a positive attitude about A1 and A3, about 53% agreed that the development of controlled release medication could reduce the financial expenditure with improvement of physicochemical and pharmacokinetic characteristics of the drug. Similarly, around 49% of participants agreed that switching the medication

from immediate release to controlled release could significantly affect the therapeutic outcomes. In addition, high percent of participants (75%) were in agreement with the remarkable effect of medical representatives in prescribing controlled release medication by physicians and only (2%) of participants had disagreement with this question. Moreover, the majority of participants (60%) had a positive attitude towards A4, they agreed that the controlled release is a worthy formulation and its therapeutic outcomes rationalized its higher price compared to immediate release.

Table 3. Frequency of responses to questions in attitude section

	Question	Agree (n %)	Neutral (n %)	Disagree (n %)
A1	Development of Modified release formulations decrease the financial expenditure on developing new medicine with enhanced pharmacokinetic and physicochemical properties	92(53)	56(32)	27(15)
A2	Medical representative activities play a major role in doctors prescribing Modified release formulation	132(75)	39(22)	4(2)
A3	Changing the patient medication from immediate release formulation to Modified release formulation significantly effects on the therapeutic outcomes of the disease	86(49)	55(31)	34(19)
A4	Modified release formulations are considered cost effective as the additive price compared to immediate release provide enhanced therapeutic outcomes.	105(60)	43(25)	27(15)

Data presented as number and percentage, n = 175

Practice variables

Concerning the practice of community pharmacists toward control release formulation, six questions were directed to the participants. Approximately three quarters (70%) of participants answered P1 incorrectly. Changing from modified dosage form to immediate release causes dramatic

change in patient response especially in critical illness. However, the majority of participants could

answer P2, and P3 correctly, as crushing and breaking the modified release dosage forms destroys their unique release characteristics. Furthermore, in P4, there were very limited correct answers. The side effect profile and drug interactions should be

monitored as they are part of the pharmacodynamics response to the medication.

Table 4. Frequency of various responses to questions in practice section

	Question	Yes n (%)	No n (%)	I do not know n (%)
p1	It is not necessary to consult the prescriber before changing the medication of a patient from modified to immediate in case of patient request or unavailability.	38(22)	123 (70)	14 (8)
p2	Modified release preparation can be cut to provide the required lower doses than the labeled amount	9 (5)	146 (83)	20 (11)
p3	Crushing modified release medication to use them in NG tube or with liquids is possible	21(12)	123(70)	31 (18)
P4	It is not necessary to check for drug -drug interaction or monitor side effects with modified release formulations.	151(87)	6(3)	18 (10)

Data presented as number and percentage, n = 175

Practice multiple choice questions.

The responses to this section showed that a great number of participants (87%) stated that the majority of modified release formulations are available in the market as oral dosage forms, followed by Transdermal then Subcutaneous and very few topical and other non- mentioned are available. Responses to this section are illustrated in Table 5.

Table 5. Practice multiple choice questions.

Majority of modified release formulations available in the market are		
Oral	153	87%
Transdermal	12	7%
Subcutaneous	6	3%
others	3	2%
Topical	1	1%
The therapeutic category for which the majority of modified medications are prescribed		
Cardiovascular	87	50%
Endocrine	47	27%
Anticancer	17	10%
Antimicrobial	13	7%
CNS drugs	11	6%

Data presented as number and percentage

Table 7. Mean score with respect to demographics

Variable	k-score	p-value	A-score	p-value	p-score	p-value
	0.638+0.202		2.461+0.374		0.654+0.245	
Age						
24-35 years	88.12	0.382	89.13	0.037*	87.65	0.301
36-45 years	83.65		92.44		84.68	
46 years and over	111.36		41.5		113.86	
Gender						
Female	81.19	0.031*	88.01	0.998	79.14	0.003*
Male	97.29		87.99		100.09	

Spearman correlation coefficient

This test was used to evaluate the relationship between the three domains of the KAP questionnaire. The results are shown in Table 6 below.

Table 6. Correlation between KAP responses .

Variable	Spearman correlation coefficient	p-value
Knowledge , Attitude	0.073	0.335
Knowledge, Practice	0.228	0.002*
practice, Attitude	0.048	0.531

*Statistically significant at p < 0.05

Mann-Whitney U test and Kruskal Wallis H test

These tests were used to evaluate the significance of each demographic characteristic on each domain in the questionnaire. The results of these two tests were summarized in Table 7 below.

Continued table 7.

Qualification						
BSc Pharmacy	87.39	0.426	87.39	0.966	89.34	0.045*
Pharmaceutics Specialist	82.6		98.5		91.6	
MSc in pharmacy	79.88		89.46		68.1	
PhD in pharmacy	109.14		87.55		113.36	
Years in community pharmacy Practice						
less than 1 year	92.89		84.6		78.5	
1-5 years	85.75	0.734	89.38	0.956	79.32	0.012*
6-10 years	82.65		85.81		105.69	
more than 10 years	93.43		89.87		100.09	
Years from graduation						
less than 1 year	102.63	0.502	86.44	0.806	77.63	0.181
1-5 years	90.04		93.04		79.59	
6-10 years	81.27		86.91		96.8	
more than 10 years	86.73		84.28		92.88	
Pharmacy location						
Center of the city	86.87	0.561	88.74	0.706	89.3	0.48
Countryside	92.08		85.33		83.3	
Mode of Dispensing in the pharmacy						
OTC by the Pharmacist	85.48	0.332	89.78	0.499	88.86	0.726
By Prescription	39.09		84.41		86.26	

*Statistically significant at $p < 0.05$

Discussion

As far as we know, this is the first study in Iraq to assess KAP regarding modified release dosage forms.

Regarding the knowledge section, the inability of community pharmacists to distinguish between different types of dosage forms and hazard of dose dumping were probably due to the lack of educational programs or the proper implementation of the theoretical knowledge into practice⁽¹⁶⁾. Similar findings were reported in another study performed in Sri Lanka in 2019. The study samples were academics working at medical faculties of the State universities and having an MBBS degree⁽¹⁷⁾. For the attitude section, there was a predominant agreement of 60% of participants about the cost effectiveness of the modified release product. This could be explained by better disease control and decreasing the effort of nursing staff and probably

their number in each shift in case of hospitalized patients. A study performed by Zaid AN in Palestinian during 2009 to evaluate the knowledge and practice of pharmacist and doctors regarding sustained release product showed that the majority of the both groups agreed with the cost saving potential of the modified release products⁽¹⁸⁾. On the other hand, the role of medical representatives and their promotional activities generally plays a major role in increasing the prescribing of certain medication or dosage forms⁽¹⁹⁾. The case is similar for modified release products as reported in our results with a major agreement.

An important finding in the practice section is that 83 % and 70 % of participants were aware that modified release products should not be splitted or crushed, respectively. This was also reported in a study conducted by Gafar MA (2017) in Sudan in which KAP regarding tablet splitting was estimated.

The hazards of modified release tablet deformation prior to swallowing were identified by 64.4% of the respondents ⁽²⁰⁾. Similarly, another study in Benghazi Medical Centre, Libya during 2019 to evaluate the knowledge about tablet crushing among pharmacists, doctors and nurses. Pharmacists showed extraordinary knowledge represented by 96.2% of them giving correct answers as compared to doctor and nurse where correct responses were 75 and 20 % respectively ⁽²¹⁾.

The correlation between the three domains of the questionnaire was estimated by Spearman correlation coefficient (22, 23). The results are given by Table 6. It can be noticed that there is a positive correlation that is statistically significant between knowledge and practice (p value = 0.002, $p < 0.05$). This means that as the knowledge increases, the practice errors are reduced and enhanced practice outcomes.

The results of our study indicate that males showed better knowledge and practice scores than females as shown in Table 7. There was a statistically significant difference between knowledge and practices of males and females (K, p value = 0.031, P, p value = 0.003). This result was not documented in a research before but could be explained by the fact that male pharmacists are involved more than females in the conferences and drug companies' promotional activities, so they would get more information from this close contact with these authorities.

Also, there was a statistical difference between pharmacists with different qualifications in concern with the practice section. Phd holders displaying significantly better (P, p value = 0.045, < 0.05) practice score than other participants with BSc., MSc. and Diploma. Knowledge of the Ph.D. qualified pharmacist was also the highest compared with others but the difference is statistically insignificant. This is perhaps due to longer years of academic study better focused on the particular specification of several advanced drug delivery systems including the modified release product. It is expected that the attitude of people having a specialty in pharmaceuticals was more positive than other categories as a result of their knowledge with the specific techniques employed to enhance the performance in these dosage forms.

It was also noticed that there is a significant difference between the participants with respect to their actual years of practice in the community pharmacy. As the years of experience increased, the mean rank of the specific category increased accordingly in all of the three domains. However, the difference is statistically significant in the practice section only (P, p value = 0.012). Another important finding of this study was that the difference in KAP domains is statistically insignificant between the different levels in the duration after graduation, pharmacy location,

dispensing modes. Similar findings could not be found in literature but this can be indicative that the same information was reachable to pharmacists in the governorate regardless of their pharmacy location or dispensing mode.

Limitations of the study

The number of participants is the major limiting factor in this study.

Conclusions

The result of this study demonstrates lack of knowledge in many aspects regarding modified release dosage forms. This leads to a variety of negative attitudes towards these products. Also, several practice errors were the result of this knowledge gap and misunderstanding among community pharmacists in Basra city. The result of this study demonstrates the need for educational programs for community pharmacists that implement the basic theoretical background into practical examples and real cases in dealing with this important class of dosage forms. Such programs would provide a great benefit for career development and fill the gap in case of misconception or lack of knowledge.

Acknowledgement

The authors wish to acknowledge all the participants in the study. Also, the academic experts for their opinions in the validation of the questionnaire.

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