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Original Article

# How Should We Think About Pharmaceutical Excipients in Clinical Pharmacy Education?

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## ABSTRACT

**Background:** As the pharmaceutical industry shifts to a patient-oriented approach, pharmaceutical education has fairly garnered increasing attention from educators, so that the teaching course centered on pharmaceutical excipients is becoming more and more popular. **Purpose:** The purpose of this study was to evaluate the significance of pharmaceutical excipients in clinical pharmaceutical education by a single-blind and parallel group design. **Materials and Methods:** The course was given in the form of small classes at Zhejiang University. The control group was taught in a traditional mode, while the intervention group mainly focused on the importance of pharmaceutical excipients in teaching. Likert five-point scale was used to analyze the test difficulty and learning effect of students in both groups. **Results:** Firstly, we investigated the test difficulty and learning time of the two groups of students, no significant difference was detectable between the two groups ($p>0.05$). Then, we investigated the learning effect of the two groups from four dimensions: accessibility of teachers' teaching concept, inspiration of the teaching methods, independence of students in the teaching process, and the extent to which the curriculum expanded student's horizons. It was found that the learning effect was much preferred in the intervention group as compared with the control group ($p<0.05$). **Conclusion:** The results showed that the emphasis on the integration of pharmaceutical excipients in pharmacy education had a positive impact on students' learning. Therefore, it is worth to reevaluate the role of pharmaceutical excipients in clinical pharmacy education.

**Keywords:** Clinical pharmacy education, Pharmaceutical excipients, Parallel group design, Teaching improvement.

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## INTRODUCTION

Significant strides have been made in pharmaceutical industry, shifting the focus from drugs to clinical pharmaceutical care, which lead to the emergence of clinical pharmacy. Due to its foundation and practicality, pharmacy courses based on pharmaceutical excipients have become one of the important basic courses for training pharmaceutical professionals.[1,2]

Originated from the United States in the 1960s, the concept of clinical pharmaceutical care came into being. Looking around the world, clinical pharmacy education in various countries has experienced continuous innovation. The Federal Union of German Associations of Pharmacists (ABDA) recently formulated "Pharmacy 2030", which stipulated that doctors and pharmacists shall share the responsibility in drug usage. Therefore, some German scholars proposed to add clinical practice into clinical Pharmacy education. In the meantime, students in Kitasato University School of Pharmacy, Tokyo, were asked to obtain patient data from a model medical chart, before performing stimulated patient interviews, which includes hospital admission and patient counseling. It was found that students were able to develop their communication skills through this approach. What's more, Umeå University in Northern Sweden tried to apply 3D virtual world (3DVW) technology to clinical pharmacy courses. More than half of students (76%) believe that the improvement of the course has helped them in their studies.[3-5]

As the birthplace of clinical pharmacy, clinical pharmacy degree education in the United States is divided into two stages: A pre-professional curriculum and a full-time professional curriculum, which is field-oriented and emphasizes positive learning results.[6] In 1964, China proposed to develop clinical pharmacy. Advanced clinical pharmacy education in China started in the early 1980s and has been developing for more than 40 years.[7] In recent years, clinical pharmacy education in China has developed rapidly and achieved satisfactory results. However, there are still many problems such as passive indoctrination of knowledge, poor connection between different disciplines and also with clinical practice, which are worth of our thinking.[8,9]

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As a comprehensive applied part derived from pharmacy, pharmaceutical excipients mainly focus on the rational application of excipients and the characteristics of specific excipients in different dosage forms.[1] Since the selection and application of pharmaceutical excipients are related to the prescription design, preparation process, quality control and rational application of pharmaceutical preparations, pharmacy education based on drug excipients has become one of the important fundamental links to cultivate qualified pharmaceutical professionals. By improving the physicochemical properties such as drug stability and solubility, excipients can significantly affect the ADME of drug preparations.[10,11]

At the same time, recent studies have found that the using of pharmaceutical excipients may also affect the safety of diagnosis and treatment. Yelena Ionova *et al.*[12] proposed an excipient assessment framework to quantify the instability of excipients in 230 biological agents, and found that the addition of pharmaceutical excipients such as polysorbide 20 may lead to allergy and other adverse reactions in patients. Zhang Tai *et al.*[13] reviewed the literatures on the physiological activity, physiochemical properties of pharmaceutical excipients and other factors affecting the safety of diagnosis and treatment in recent years, and found that the adverse reactions caused by pharmaceutical excipients are often related to their intrinsic properties. Jumpei Saito *et al.*[14] has launched a multicenter nationwide observational study in Japan. They found the Neonatal Intensive Care Units (NICUs) treated newborn in exposure to Potentially Harmful Excipients (PHEs), PHEs was also found in several of the most common prescription drugs in intensive care unit daily clinical practice. As it is closely related to drug safety, the explanation of pharmaceutical excipients deserves our attention in clinical pharmaceutical education.

In recent years, the teaching reform of pharmaceutical excipients in China mainly focused on advocating the combination of teaching cases and students' existed learning background. It is also suggested to stimulate students' interest in learning through the form of problem orientation.[2,15] Therefore, we realized that the purpose of the teaching reform should be standing in the perspective of students and promoting the teaching process gradually shift to be student-oriented.

To promote students' learning and explore the significance of pharmaceutical excipients in clinical pharmaceutical education further, we tried to teach a small-class pharmacy course in the school of Pharmacy at Zhejiang University. The control group was taught in a traditional mode, while the intervention group mainly focused on the significance of pharmaceutical excipients in teaching. A questionnaire survey was conducted on students at the end of the course.

# MATERIALS AND METHODS

## Subjects and methods

The study was conducted during the summer semester of the 2020-2021 academic year at the School of Pharmacy, Zhejiang University. A total of 76 students were invited to participate in the study. Participation was voluntary and students can opt out at any stage of the study without penalty (note there were no dropouts). Based on the classes they were in, we divided all participants into two groups, the intervention group (39 in total) and the control group (37 in total).

## Study Design

After the students were divided into two groups, we still taught the students in the control group on the traditional mode that is, based on the sequence of chapters in the textbook. As for the intervention group, we tried to link various dosage forms through medicinal excipients, so as to help students learn and understand. Our specific plan was as follows:

First, we helped the students in the intervention group build a knowledge framework of common pharmaceutical excipients by giving examples and summarizing the excipients in common drugs. Then, regarding pharmaceutical excipients as "lines", we connected their specific application as knowledge "points" to promote the learning of knowledge "aspects" related to each dosage form (Figure 1).

Here, regarding pharmaceutical excipients as "lines", we connected their specific application as "points" to promote the learning of knowledge "aspects" related to each dosage form. Then, we tried to connect kinds of dosage forms by building a knowledge framework of common pharmaceutical excipients.

Based on this, we tried to use pharmaceutical excipients and their applications to closely link complex knowledge covered by various dosage forms, such as the basic theory, prescription design,

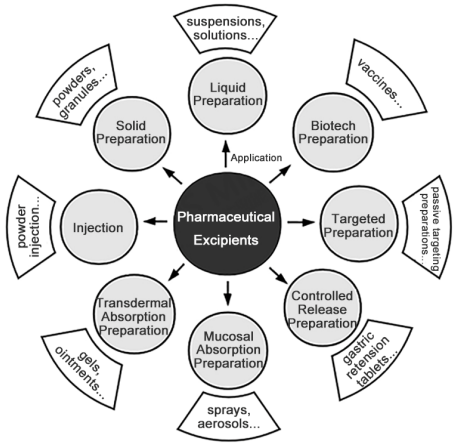


**Figure 1:** Our new teaching mode.

preparation process, quality control and rational application, expecting to facilitate students to remember and master.

For example, PEG can be used as a clue, as it can be used in liquid solubilizers, solid dispersions, tablet lubricants, pore-forming agents, cream base, and so on. It is helpful to consolidate knowledge points to connect the background knowledge areas of each knowledge point in series. It should be noted that, in order to control the experimental variables, the teaching time and teaching materials used by the two groups of students were both the same.

### Statistical analysis

After the two groups of teaching were completed at the same time, using Likert five-point scale, we investigated students' difficulty of passing the tests and learning effect. With Origin 2021, we converted the collected data into charts. Also, based on the survey data, we conducted statistical summary and significance analysis through IBM SPSS Statistics 23. A normality test was conducted for the dependent variables (students' evaluation of their learning results from four dimensions) and the independent variables (teaching mode) to determine whether students' evaluation of their learning results were normally distributed among teaching mode categories (i.e. intervention group and control group). In the evaluation survey, we regarded students with "strongly agree" as students who gave high evaluation. To facilitate statistical analysis, we selectively summarized the number of students who gave high evaluation. As date was not normally distributed, the Mann-Whitney test was used to test for the differences in perception among the independent groups. The $p$-value < 0.05 was considered significant difference.

## RESULTS

Firstly, we investigated the students' test difficulty of courses (Figure 2). It was found that there was no significant difference between the two teaching modes on the acceptance difficulty ($p$ > 0.05).

In order to Figure out the influence of different teaching methods on students' difficulty of passing the tests, using Likert five-point scale, we investigated students' opinions. Then, based on the data, we conducted the data summary and significance analysis through Origin 2021 and IBM SPSS Statistics 23, respectively. ($p$>0.05) (a:high, b:relatively high, c:neural, d:relatively low, and e:low.)

Subsequently, in the same way, we investigated the time invested in learning (Figure 3). It was also found that there was no significant difference between the two teaching modes on the learning time ($p$>0.05).

In order to Figure out the influence of different teaching methods on the time invested in learning, using Likert five-point scale, we investigated students' learning time. Then, based on the data, we conducted statistical summary and significance analysis through Origin 2021 and IBM SPSS Statistics 23, respectively. ($p$>0.05) (a:much, b:relatively much, c:neural, d:relatively few, and e:few.)

Finally, we investigated the learning results evaluation of the two groups of students through four dimensions, namely, accessibility of teachers' teaching concept, inspiration of the teaching methods, independence of students in the teaching process, and the extent to which the curriculum expanded students' horizons. As the sample data did not meet the normal distribution, the total number of students with high evaluation was classified and counted by using IBM SPSS Statistics 23 and Mann-Whitney test, it was found that the group emphasizing the significance of excipients had better learning results ($p$<0.05) (Table 1).

## DISCUSSION

Excipients are necessary as a support to the active ingredients in drugs, while also contribute to their stability, preservation, pharmacokinetics, bioavailability, appearance and acceptability.[16] Typical excipients are the major components of a drug product, with the active molecule only present in relatively small amounts. Historically, excipients were termed inactive components.[17]

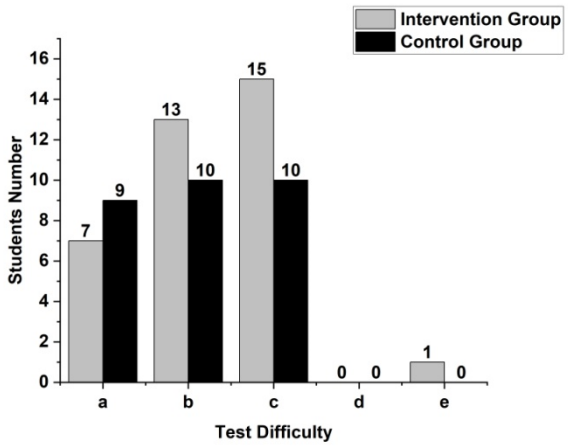


**Figure 2:** The difficulty of passing the tests.

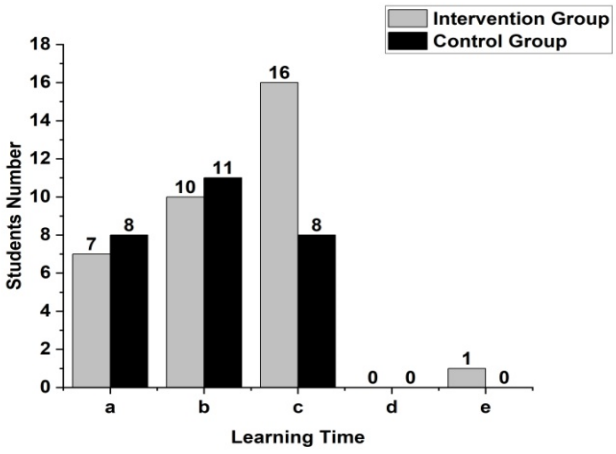


**Figure 3:** The time invested in learning.

**Table 1: Students' evaluation of their learning results from four dimensions.**

| Number of students who gave high evaluation | Intervention Group (39 in total) | Control Group (37 in total) | *p*-value |
|---|---|---|---|
| If the teacher's teaching ideas are easy to understand or not? | 22 | 19 | |
| If the teacher's teaching methods are instructive or not? | 22 | 19 | |
| If the teaching process guides students to learn independently or not? | 22 | 18 | |
| If the course broadens students' horizons or not? | 23 | 19 | |
| Total | 89 | 75 | 0.016 |

However, as mentioned above, excipients can have an impact on the Absorption, Distribution, Metabolism and Elimination (ADME) processes of the drug, which is important information when selecting excipients for any new formulation.[10,11] Further, it enlightened us that it is worth to emphasize the role of pharmaceutical excipients in daily clinical pharmacy education.

In order to Figure out the influence of the teaching improvement on students' learning difficulty, we investigated students' difficulty of passing the tests and the time invested in learning. However, distinction between intervention group and control group was little. One possible reason is that our teaching reform is subtle, so it has little impact on the learning difficulty in a short period. Another reason is that the course is a compulsory course, which contains more content and is more difficult, so students usually spend more time on the course learning, so there was no significant difference between the control group and the experimental group.

In the current study, the learning results evaluation from four dimensions showed that the teaching improvement had positive impact on students' learning effect ($p<0.05$). Mirroring the results from other studies about clinical pharmacy education reform, most students enjoyed the classes with more creativity and practicality.[18,19] In the meantime, many students agreed that pharmaceutical excipients is an important part in clinical pharmaceutical education, which objectively evaluated our teaching reform.

This study has several limitations. One of the most important limitations was that our intervention group and control group only included students from two classes, which meant our experimental data was limited. If possible in the future, we plan to expand the sample size and further explore how to better utilize the pharmaceutical excipients to connect the clinical pharmacy education process.

## CONCLUSION

Herein, a single-blind teaching study was conducted using a parallel group design to systematically evaluate the significance of pharmaceutical excipients in clinical pharmaceutical education. Participating in prescription design, preparation process, quality control, rational application and other processes of pharmaceutical manufacturing, the role of pharmaceutical excipients is self-evident. Therefore, it is worth to emphasize the role of pharmaceutical excipients in clinical pharmacy education, which provides a new idea for further education reform.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ABBREVIATIONS

**ABDA:** The Federal Union of German Associations of Pharmacists; **3DVW:** 3D Virtual World; **ADME:** Absorption, Distribution, Metabolism and Elimination; **NICUs:** The Neonatal Intensive Care Units; **PHEs:** Potentially Harmful Excipients.

## SUMMARY

In this teaching research, using a parallel group design, a single-blind teaching study was constructed to systematically evaluate the significance of pharmaceutical excipients in clinical pharmacy education. The control group was taught in a traditional mode, while the intervention group mainly emphasized the importance of pharmaceutical excipients in teaching. Likert five-point scale was used to compare and analyze the learning difficulty, learning effect and recommendation degree of students in both groups. The results showed that the emphasis on the integration of pharmaceutical excipients in pharmacy education had a positive impact on students' learning, which indicate that emphasizing pharmaceutical excipients is of great help to clinical pharmacy education.

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