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PHARMACODYNAMICS

Cinemeducation in clinical pharmacology: using cinema to help students learn about pharmacovigilance and adverse drug reactions

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Abstract

Purpose Feature films are increasingly being used in teaching health sciences. However, few publications address the effectiveness of this approach. We hypothesized that using feature films could help students learn. We aimed to assess the effectiveness of using a feature film to teach students about adverse drug reactions and pharmacovigilance.

Methods The study population comprised third-, fifth-, and sixth-year undergraduate students of medicine, third-year undergraduate students of human biology, and graduate students in a master's degree program about the pharmaceutical and biotechnology industry. Students watched clips from the film *150 Miligrams* (*La fille de Brest*) and discussed them afterward. To measure learning, we administered a 10-question multiple-choice test about pharmacovigilance concepts. We assessed students' satisfaction with the activity through a questionnaire. An exploratory comparative analysis was performed.

Results A total of 237 students participated. Postintervention assessment scores were significantly higher than preintervention scores for the entire population and for all subgroups. The mean number of correct answers was 4.41 on the preintervention assessment and 5.78 on the postintervention assessment (mean gain: 1.37; 95% CI: 1.10–1.65). Similar results were found when analyzing groups of students from each group. Student satisfaction with this teaching activity was high in all groups.

Conclusions *Cinemeducation* is a useful tool for teaching about adverse drug reactions and pharmacovigilance processes. Most students were highly satisfied.

Keywords Cinemeducation · Education · Pharmacology · Adverse drug reactions · Pharmacovigilance

Introduction

Feature films have been used as a teaching tool in medicine since the birth of the cinema at the end of the 19th century [1–3]. Films depict diseases from multiple perspectives, showing their clinical aspects, health professionals' efforts to treat them, and their psychosocial impact on patients [4]. Projecting and discussing films can help students of the health sciences by using concrete situations to raise issues in real-life contexts, to offer models of behavior and professionalism, and to show patients' experience, diagnosis, and treatment from different perspectives [3–13].

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The term *cinemeducation* refers to the use of films or video clips in medical education [14–17]. Many reports describe experiences using cinemeducation for diverse purposes, including to show different aspects of psychiatry and mental health [18–20], to help students acquire communication tools [4, 21] and understand disease [22, 23], and to tackle bioethical conflicts [24, 25]. The multiple pedagogical proposals in these experiences highlight the importance of tools such as discussion groups, case planning and resolution, and the administration of satisfaction and learning questionnaires [25]. However, there is an evident lack of systematization in the description and development of these activities as well as in the measurement of empirical results [25]. Moreover, there are almost no reports on the use of cinemeducation in teaching basic medical sciences such as pharmacology [26]. Thus, we planned this study to acquire empirical knowledge about using cinemeducation in clinical pharmacology.

Pharmacovigilance is one of the most important activities in clinical pharmacology, encompassing efforts to detect, assess, understand, and prevent adverse drug effects and other potential problems that can develop in drugs after approval [27]. Some students find it difficult to understand many aspects of pharmacovigilance, especially how decisions about safety concerns are taken and the roles of different players in the decision to recommend changes to the Summary of Product Characteristics or the withdrawal of a drug.

We hypothesized that cinemeducation would enhance students' learning and understanding of pharmacovigilance processes and adverse drug effects.

Methods

Study population

All undergraduate (human biology, Medicine) and postgraduate (Master in Pharmaceutical and Biotechnological Industries) students who were enrolled in a pharmacology course at UPF were eligible to participate in the study. Additionally, a group of medical students at Universitat Autònoma de Barcelona were also invited to participate. Participation was voluntary.

Study design

We designed a pilot study to explore students' learning about pharmacovigilance processes and adverse drug effects. The institutional review board of the hospital affiliated with the two universities approved the protocol for this prospective study. Before starting the teaching activity, we informed potential participants of the background, aims, and procedures of the study, of review board approval, and of their right to decline to participate in or to drop out of the study at any time without fear of consequences. Participants gave their consent to participate in the study by filling out and delivering the questionnaires anonymously. The study was performed according to the principles of the Declaration of Helsinki. Confidentiality was ensured according to Spanish legislation on the protection of personal data.

Choice of the feature film

After systematically searching the literature and the IMDB database [28], we chose the film *150 Miligrams* (*La fille de Brest*) [29] because adverse drug reactions are central to the plot and the film also shows other aspects of pharmacovigilance such as the importance of a signal alert, the studies needed to confirm/reject causality of an adverse drug event, and the roles of the pharmaceutical industry and public health agencies. Moreover, the film portrays an investigation into a drug and shows confrontations among the doctor, the hospital team in charge of the epidemiological study, and the staff of the state pharmacovigilance agency. This combination of clinical, pharmacological, and psychosocial aspects suggests that the film could be very useful for teaching about pharmacovigilance.

150 Miligrams tells the true story of Irène Frachon, a French pulmonologist at a hospital in Brest who discovered the first cases of cardiotoxicity associated with benfluorex, an anorectic that was sold massively in France for more than 30 years that is thought to have caused the death of more than 500 people. The film relates Dr. Frachon's experiences after reporting her findings and requesting the withdrawal of the drug, culminating in 2009 in a legal battle with the pharmaceutical company that marketed the drug.

The teaching activity

The study took place between November 2018 and May 2019. Students were shown a clip with different scenes of the film (50 min length) that were selected for their relevance to the teaching objectives.

To assess students' knowledge about anorectics, adverse drug reactions, and pharmacovigilance processes, we elaborated a test comprising 10 multiple-choice questions. Regarding the questions about pharmacovigilance issues, we asked about the best method to study the causality of adverse drug effects, the factors that can contribute to the causal relationship, the method that gives the best evidence of its attribution, the institution that decides whether to withdraw a drug, the factors that suggest the causal relationship, the professionals who can communicate an adverse drug reaction, and factors that can hinder the identification of the relationship between a drug and an adverse reaction.

Each question had 5 possible answers, of which only one was correct. We administered the test before (preintervention assessment) and after the teaching activity (postintervention

assessment). To measure learning from the activity, we compared the results on the preintervention and postintervention assessments.

Teaching activity sessions consisted of (1) an introduction (15 min); (2) preintervention assessment (10 min); (3) film viewing (50 min); (4) discussion to resolve doubts about relevant aspects of the film (30 min); (5) postintervention assessment (10 min); and (6) administration of the satisfaction questionnaire (5 min). The entire activity took about 2 h.

Assessment of student satisfaction

To assess the students' opinions about how the teaching activity improved their learning, we developed a questionnaire with 6 statements (Table 1). To avoid rapid and automatic responses, statements 1, 2, and 6 were formulated negatively, and statements 3, 4, and 5 were formulated positively. Students rated their agreement with each statement on a scale ranging from 1 (totally disagree) to 5 (totally agree).

Statistical analysis

No formal sample size calculation was done. The number of students recruited was defined as the number in each cohort who agreed to participate.

Categorical variables are expressed as frequencies and percentages, and continuous variables are expressed as means and standard deviations (SD) or medians and interquartile ranges (IQR), as appropriate. To compare the results on the preintervention and postintervention assessments, we used the binomial test and the Mann-Whitney *U*, analyzing the entire sample and each group of students. The results of the satisfaction questionnaire are presented as the frequencies of each response to each statement, considering the entire group and each group of students.

We used R (version 3.5 for windows, R Core Team, 2015) for all analyses.

Table 1 Students' satisfaction questionnaire

Statement 1. The activity has not improved my knowledge of adverse reactions and pharmacovigilance procedures
Statement 2. Films are not useful for learning concepts about pharmacovigilance
Statement 3. The debate has helped me better understand the situation presented in the movie
Statement 4. The use of commercial films makes teaching activities more enjoyable
Statement 5. I would recommend this activity to other students to improve their understanding on pharmacovigilance
Statement 6. I feel indifferent about the use of films in teaching activities

Results

Study population

A total of 237 students participated in the study: 170 students of medicine (67 third-year students at UPF, 59 fifth-year students at UAB, and 44 sixth-year students at UPF), 38 students of human biology (third-year UPF), and 29 students in the master's degree program in pharmaceutical and biotechnological industry (UPF). 220 students (92.8%) completed the questionnaire and the satisfaction survey.

Teaching activity evaluation

In the analysis of the entire population, the number of correct answers on the multiple-choice questionnaire was higher on the postintervention assessment (mean 5.78, median 6.25 (5.00–6.25) vs. mean 4.41, median 5.00 (3.75–5.00) on the preintervention assessment; mean difference, 1.37 (95% CI: 1.10–1.65), $p < 0.001$). Table 2 reports the scores and the mean differences between the scores on the preintervention and postintervention assessments for each group of students.

Comparing mean scores before and after the intervention showed that students in the Master's program showed the greatest gain, whereas sixth-year students at UPF and fifth-year students at UAB had the smallest gains. Gains by third-year students of medicine and human biology were intermediate.

The questions with the largest difference between the preintervention and postintervention assessments were about the type of adverse reaction that led to the withdrawal of the drug (difference in the percentage of correct answers 79.75 [76.85, 81.34], $p < 0.0001$), the methodology used against an adverse reaction of a drug (26.16 [19.71–32.24], $p < 0.0001$), the best evidence for the attribution of an adverse reaction (7.17 [1.53–13.37], $p < 0.01$), and the factors that suggest a causal relationship in the adverse drug reaction (6.75 [1.03–11.72], $p < 0.05$).

Table 2 Scores (calculated over 10) of pre- and postintervention assessments by students' group. Values are expressed as means (SD)

Group	*N*	Before	After	*p* overall
Master	29	3.75 (1.95)	6.12 (1.17)	< 0.001
6th UPF medicine	44	4.72 (1.64)	5.57 (1.54)	0.014
3rd UPF medicine	67	4.37 (1.62)	6.04 (1.32)	< 0.001
3rd UPF human biology	38	3.65 (1.41)	4.97 (1.78)	< 0.001
5th UAB medicine	59	5.04 (1.18)	6.00 (1.20)	< 0.001

Student satisfaction

No differences were observed between the different groups. Most participants expressed total or partial agreement with the three statements that affirmed the usefulness of the activity and their satisfaction with it: 76.3% considered the debate valuable; 85.9% recognized the value of commercial films in teaching activities, and 95.9% would recommend this activity to other students. Similarly, most participants expressed total or partial disagreement with the statements that denied the usefulness of the activity for improving their knowledge about pharmacovigilance (78.7% disagreed with the statement that the activity does not improve knowledge; 91.8% disagreed with the statement that commercial films are not useful for learning pharmacovigilance concepts; and 80.9% disagreed with the statement that they were indifferent to the use of commercial cinema in teaching activities).

Discussion

Few scientific studies have been published about *cinemeducation* [15–17] and its impact on learning in the field of clinical pharmacology. We found no reports of other experiences using feature films to enhance learning about the processes involved in pharmacovigilance. Our exploratory results show that the teaching activity was effective in improving students' understanding in this area (specially in regard to the establishment of the causal relationship in the adverse drug reaction) and that the vast majority of students were satisfied with the activity.

Differences between the scores on the preintervention and postintervention assessments indicate the gain in knowledge attributable to the teaching activity. This gain depends on students' baseline knowledge (measured in the preintervention assessment) and by the pedagogical quality of the teaching activity, which is, in part, teacher-dependent. Teachers can guide the discussion toward the points that they consider more relevant. Likewise, external factors such as the time point when the activity was carried out (i.e., how far along studies are in their degree program and in the academic year) can also influence the gain in knowledge.

As might be expected, students in the master's program and those in the sixth year of medical school had the highest scores in the preintervention assessment; these students have spent more years studying health sciences and have probably acquired more knowledge about the topics covered in the test. Interestingly, students in the master's program showed the highest gain in knowledge, whereas sixth-year students of medicine showed the lowest gain. Despite their high baseline scores, fifth- and sixth-year medical school students showed statistically significant gains after the teaching activity, but these gains were not as great as those seen in the other groups. These results could be influenced by the quality of the debate in the teaching activity or by differences in motivation and/or participation. However, given the similarity of gains in students in similar situations at different universities, the time point seems an important issue.

The differences between the gains observed in third-year medical students and in third-year human biology students might be due to different motivations and interests. Medical students are training to become physicians, whereas human biology students typically go into research-oriented careers. Thus, medical students might be expected to be more interested in the more clinical and human aspects of pharmacology, and human biology students might be expected to be more interested in chemical and technical aspects.

Although some authors recommend working with an entire film [13], others recommend using clips or fragments to generate discussion [8, 15]. We were able to select the scenes that are related to the subject of interest and arrange them in a sequence that allowed students to follow the narrative thread of the film. In light of the valuable information we derived from this exploratory study, our future research will delve deeper into quantitative and qualitative analyses of the classroom discussion to explore students' beliefs, values, and attitudes about pharmacology and professionalism. To make the most of these types of activities, we need to apply a systematic approach to evaluating their impact so we can improve them. A systematic approach is also necessary to develop a solid theoretical basis for using feature films to teach medicine and determine the impact of this approach on students' learning. Moreover, future studies can benefit from these exploratory results by checking them and comparing different educational interventions or methods (e.g., films versus literature, fiction films versus nonfiction or documentary films). It could also be interesting to do a comparative study with short video clips (≤ 5 min) [8, 16, 22]; these video clips could be taken from YouTube, TikTok, or other social media to analyze how the short clips common in modern culture might be more beneficial for the "Connected Generation" [30–32].

Our study has some limitations. The main limitation is the absence of a comparison group using another teaching method. However, the current study was designed as an exploratory survey to determine whether cinemeducation can be useful for teaching pharmacovigilance to health science students. Further research should compare the value of this approach against other teaching approaches. The literature about learning through cinema in medicine still lacks the systematization and detail necessary to provide a solid theoretical basis for this approach, and such exploratory studies are needed to provide experimental data to establish its pedagogical value. Another weakness is that our analysis was limited to immediate gains in knowledge. Time constraints precluded us from evaluating the long-term knowledge gain. According to the cognitive load theory [33], the working memory organizes information in packages but can only process a few elements at a time.

This creates a "bottleneck" for the long-term-memory. Thus, it would be important to assess retention to measure the durability of learning. Furthermore, the specific context in which our study was carried out might underestimate or overestimate the gains in knowledge attributable to the activity and thereby limit the generalizability of our results to other universities. Another possible technical limitation is that we selected the film for the teaching activity by searching the Internet Movie Database (IMDb) for keywords. Because this platform is managed entirely by users, the classification and tagging of keywords are not rigorous, so the search results are sensitive but not very specific. Finally, the usefulness of the specific contents of the learning activity might be questioned because the process of pharmacovigilance changed in France after the events depicted in the film. Nowadays, the pharmacovigilance of most drugs is under national control, but the European Medicines Agency is responsible for evaluating the safety of most drugs marketed in Europe.

In conclusion, the teaching activity used in this study helped students learn about adverse drug reactions and pharmacovigilance. However, the full value of the activity can only be established after further validation in future studies.

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Compliance with ethical standards

The institutional review board of the hospital affiliated with the two universities approved the protocol for this prospective study. Before starting the teaching activity, we informed potential participants of the background, aims, and procedures of the study, of review board approval, and of their right to decline to participate in or to drop out of the study at any time without fear of consequences. Participants gave their consent to participate in the study by filling out and delivering the questionnaires anonymously. The study was performed according to the principles of the Declaration of Helsinki.

Conflict of interest The authors declare that they have no conflict of interest.

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