

Understanding Ethical Principles in Clinical Research Using Popular Films

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Summary

Popular films have been used to illustrate issues that may be difficult to fully understand in lectures. We hypothesise that bioethics applied to clinical research may be better understood if students are exposed to the real or fictional characters depicted in commercial films. We designed a randomised, parallel study to compare the effectiveness of two popular films, *Miss Evers' Boys* and *Extreme Measures*, to improve the understanding of bioethical principles in students of Human Biology. Students were randomly assigned to each experimental group and they completed a self-administered questionnaire to establish the subjective improvement of their knowledge on bioethical principles applied to clinical research. Ninety-four students participated in the experiment. Fifty students were assigned to *Extreme Measures* and forty-four to *Miss Evers' Boys*. Students rated both films as useful to learn bioethics in clinical research. Principles of justice and autonomy were better understood than beneficence and non-maleficence. No differences were seen between the films' scores for each question. Popular films may be useful in teaching the application of bioethical principles to students. We conclude that the choice of film is critical and a list of questions prepared by teachers may eventually help the students to focus on the most important points.

Keywords: Bioethical principles, Clinical research, Teaching, Popular films.

Resumen

Las películas comerciales se han empleado para ilustrar temas difíciles de comprender totalmente en las clases teóricas. Nuestra hipótesis se basa en que la bioética aplicada a la investigación clínica puede comprenderse mejor si los estudiantes observan situaciones reales o ficticias en películas comerciales. Diseñamos un estudio aleatorizado y paralelo para comparar la eficacia de dos películas, *Miss Evers' Boys* (*El experimento Tuskegee*) y *Extreme Measures* (*Al cruzar el límite*), para mejorar el conocimiento de los principios bioéticos en estudiantes de Biología humana. Se les asignó de forma aleatoria a cada grupo experimental y completaron un cuestionario para establecer su mejora subjetiva en el conocimiento de los principios bioéticos aplicados a la investigación clínica. Participaron 94 estudiantes, de los que 50 fueron asignados a *Extreme Measures* y 44 a *Miss Evers' boys*. Los estudiantes consideraron ambas películas como útiles para aprender bioética en investigación clínica. Los principios de justicia y de autonomía se comprendieron mejor que los de beneficencia y no maleficencia. No se observaron diferencias significativas entre ambas películas para ninguna pregunta. Concluimos que la elección de las películas es un elemento crítico en educación y que una lista de preguntas preparadas por los profesores puede ayudar en ocasiones a centrar la atención de los estudiantes en los puntos más importantes.

Palabras clave: Principios bioéticos, investigación clínica, enseñanza, películas comerciales.

The authors state that this article is original and has not been previously published.

Introduction

Bioethics is one of the most important subjects in the training of undergraduate students, especially in the biomedical domain. The teaching activities designed to introduce the main questions, and to discuss the bioethical commitments that they bring to everyday life, are critical to enhance their full understanding. However, given the importance of the theoretical knowledge of bioethics and the students' need to be able to fit to specific situations, its teaching will be clearly improved if contextualization of clinical situations is allowed¹.

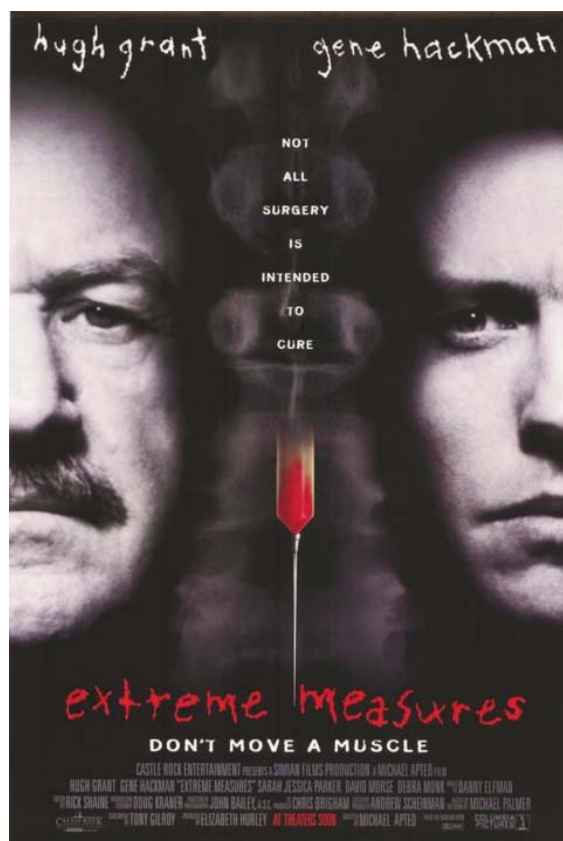
Clinical research is an example of how bioethical principles should always be considered when making choices². However, the process of acceptance of this statement has been an uneasy process. Human experimentation on the Nazi prisoners of concentration camps in the Second World War showed the lack of general agreement of how ethical principles should be preserved in humans when participating in research³. The Nuremberg Declaration that ensued did not completely avoid unethical clinical research, and several improper experiments in human subjects were still reported in the Sixties^{4,5}. Therefore, legislation cannot completely prevent unethical practices, and students of health disciplines should be educated to understand why bioethical thinking is essential to practise clinical research.

Popular films have been increasingly used in the teaching of undergraduate health curricula in recent years⁶⁻¹⁰, especially in situations that may imply moral issues, such as clinical research¹¹⁻¹³ and medical ethics¹⁴. Nevertheless, empirical studies analysing which film would be better for specific educational objectives are scarce. In the present paper, we report the results of a randomised and parallel study that compared the effectiveness of two films to discuss bioethical principles in clinical research.

Methods

The films

The films were *Extreme Measures* and *Miss Evers' Boys*. The first was directed by Michael Apted in 1996 and was based on a novel of the same name written by Michael Palmer¹⁵. The film described the investigation of Guy Luthan (Hugh Grant), a doctor working in a hospital in New York, when the body of a man who had died in his emergency room disappears from the pathology department. The trail leads to the surgeon Lawrence Myrick (Gene Hackman), a distinguished researcher working on a new drug for the treatment of spinal cord injuries.



Miss Evers' Boys is a HBO television film directed by Joseph Sargent in 1997. It is based on a true story, adapted from the stage play written by David Feldshuh¹⁶. It explains the story of the Tuskegee secret experiment, begun in 1932 and terminated in 1972, devoted to the study of untreated syphilis¹⁷. The story is told by the nurse Eunice Evers (Alfre Woodard), one of the real participants in the supervision of the patients.

Sample

Ninety-four students of the Bachelor's degree of Human Biology participated in the study while following a course of Bioethics. They were chosen from two consecutive academic years. In 2010-2011, 47 students were enrolled and 25 students were assigned to *Extreme Measures* and 22 to *Miss Evers' Boys*. In 2011-2012, again 47 students were enrolled, with the same distribution for each film.

The Bioethics course was of 40 h and was devoted to introducing students to its general principles with some examples of their application to specific situations in biomedicine, which will eventually be related to their professional practice (basic and clinical research, stem-cell research, *in vitro* fecundation procedures). It also included some topics associated with medical practice

(abortion, euthanasia, tissue transplantation).

Study design

All students received an introductory lecture considering bioethical principles (autonomy, justice, beneficence and non-maleficence). Later, students were randomly allocated into two groups (A and B). One group viewed *Extreme Measures* and the other saw *Miss Evers' Boys*, and a general discussion followed each projection. The assignment to each group was established randomly, using alphabetical order.

At the end each session, students were invited to participate in the study. If they agreed, they filled out a questionnaire of five questions regarding the film they had just seen (Table 1), which scored on a 1-10 numerical scale. The questions agreed with the previously established educational objectives that considered the understanding of the four bioethical principles to clinical research.

Statistical analysis

Results are expressed in descriptive statistics using mean \pm standard deviation. For comparison between groups, we used the Student T test. Statistical

Table 1. Characteristics of the subjects and scores given by the students. Values are expressed as mean \pm standard error of the mean.

	Extreme Measures (n=50)	Miss Evers' Boys (n=44)
Age	21.5 \pm 1.04	21.4 \pm 1.02
Women/men (% of women)	32/18 (64)	34/10 (77.3)
Previous viewing	6	2
Q1 What is your opinion about the interest of the film to discuss bioethics in clinical research? (from 1 = very negative to 10 = very positive).	8.94 \pm 0.84	8.55 \pm 1.34
Q2 Do you think the film has contributed to clarifying the principle of autonomy? (from 1 = nothing to 10 = a lot).	8.08 \pm 1.14	7.95 \pm 1.52
Q3 Do you think the film has contributed to clarifying the principle of justice? (from 1 = nothing to 10 = a lot).	8.04 \pm 1.29	8.27 \pm 1.55
Q4 Do you think the film has contributed to clarifying the principle of beneficence? (from 1 = nothing to 10 = a lot).	7.56 \pm 1.25	7.66 \pm 1.54
Q5 Do you think the film has contributed to clarifying the principle of non-maleficence? (from 1 = nothing to 10 = a lot).	8.06 \pm 1.22	8.25 \pm 1.42

differences were established at $p < 0.05$.

Ethical considerations

As the survey was performed in the setting of regular teaching activities, approval from the local Ethics Committee was not required. The work was carried out in accordance with the Declaration of Helsinki. No potential harm to participants was expected and students were asked to participate after being informed of the aim of the study. An oral, informed consent was obtained and students completed the case form in a voluntary and anonymous manner.

Results

Groups A and B had 50 students and 44 students, respectively. The mean age was 21.5 years and 21.4 years, respectively. Women outnumbered men. The Table 1 summarises the scores of the five questions used in the questionnaire.

Regarding *Extreme Measures*, six students had seen it before the session. Concerning the interest of this film to discuss bioethical principles, students gave a score of 8.94. With reference to the interest of the film to understand each principle, the scores were 8.08, 8.04, 7.56 and 8.06 for autonomy, justice, beneficence and non-maleficence, respectively.

Regarding *Miss Evers' Boys*, two students had seen it before the session. Scores were similar to those of the first. In the question about the usefulness to understand bioethical principles in general, the mean score was 8.55. For each principle, mean scores were 7.95, 8.27, 7.66 and 8.25 for autonomy, justice, beneficence and non-maleficence, respectively.

Even when some trends were seen, no statistical differences were observed regarding any scores between films or when principles were compared within each film.

Discussion

The results of this study give clear evidence that both films may help to better understand bioethical principles as applied to clinical research. Both films gave similar scores for each principle and showed that beneficence had the lowest scores. These are the main findings of the study and deserve some comments.

The films differ in the type of plot. *Extreme Measures* is fully fictional¹⁸. Briefly, it shows the experiments performed on the homeless without their consent, with the justification that their life is useless and their participation in the research may help many patients to find relief from their ailments. When Dr. Luthan believes he is fully paralysed, he agrees to accept anything to recover the mobility of his arms and legs. Moreover, subjects who received the experimental drug underwent severe side effects, which even may end in death. These situations help students to understand the principles of justice, autonomy and non-maleficence. Even when the beneficence principle may also be understood in some aspects of the plot, it is not so clearly shown as the other three. This may explain why the students gave it the lowest scores.

Miss Evers' Boys is based upon a real story, which has been widely analysed¹⁷. Hundreds of black men were enrolled in a study to observe the consequences of untreated syphilis. The participants in the study never knew they were, in fact, study subjects. When penicillin was available, they were left untreated, and the study was continued until 1972. They never were given the possibility to be adequately treated or to withdraw from the study. The film clearly shows that the autonomy (not asking for consent) and justice (only black men) principles were broken, as well as was the non-maleficence principle (death followed untreated syphilis). The beneficence principle might be understood, considering the need for treating patients with penicillin when this drug was available (benefits versus risks of therapy), but some students were apparently not able to adequately understand this possibility. An alternative explanation may be that all students have difficulties to get its correct meaning before seeing the films. We cannot disregard this possibility but given that the mean score was over seven, we believe that most students had a good-enough understanding of it.

Another question was if real or fictitious scenarios are preferable as teaching tools. From our results, no definitive answer was concluded, as no statistical differences were seen between the films. Even when specific studies are needed to confirm this possibility, previous experience with other films, like *Awakenings*^{11,19}, *Lorenzo's Oil*¹¹ or *Frankenstein*²⁰ has shown that their educational value seems to be independent of being based on real or fictional plots.

In conclusion, the study shows that both films are useful to understand how bioethical principles should be applied to clinical research. It also

showed that the beneficence principle had lower scores than the other three, but no statistical differences were seen. Other films might be chosen if the discussion of the beneficence principle was a specific objective of the activity. However, the films described in this article may be useful even in this case, given the high scores that were reached in each of them for every bioethical principle.

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