Student's Critical appraisal on the evaluation of analgesics in Laboratory animal verses simulated clinical trail

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ABSTRACT

Effective feedback is an integral part of medical education in helping the medical students to reach their maximum potential. Without feedback mistakes may go uncorrected which results poor performances of learners as well as tutors. At present teaching learning methodology used in many medical colleges includes lectures, tutorials, practical and occasionally small groups teaching and case discussions. The curriculum of undergraduate medical and dental students of BP Koirala Institute of Health Sciences, Dharan, Nepal is need based, integrated, community oriented, partially problem based. The practical lessons are an important part of Pharmacology curricula of undergraduate courses. So the aim of this study was to evaluate the student opinion towards animal experimentation as well as simulated clinical trial (SCT) on analgesics in terms of understanding the objectives. To conduct the study a semistructure questionnaire were provided to 2nd years MBBS and BDS students to obtain their view. Of the 164 questionnaires 154 students submitted completed questionnaire. On analysis of the feedback, it was observed that 77.9% students liked animal experiments and most of them wee happy with simulated clinical trial. The majority of the students 74.1% favoured both exercises for improved understanding of the subject and 66.2% agreed the sequential sessions. So the study concludes with the view that sequential sessions of laboratory experiments as well as SCT are required for a rectified learning of Pharmacology.

Keywords: Animal Experiments, Simulated Clinical Trials (SCT), Students feedback, Medical Education.

INTRODUCTION

Feedback is a communication to another individual for the purpose of facilitating self awareness and understanding. Effective feedback being nonjudgmental, is an integral part of medical education in helping the medical students reach their maximum potential. Without feedback mistakes may go uncorrected, good performances may not be reinforced and the learners as well as the tutors may develop an inaccurate perception of their performance. It also obliterates the conflict between the teacher appraisal and students view point. Medical teachers should continuously strive to identify better ways for teaching medical students, in order to make them a good rational prescriber later in life.[1,2] At present the teaching learning methodology used in many medical college includes lectures, tutorials, practical and occasionally small group teaching and case discussions. Though with these methods, students gain an overall grasp of the subject but are unable to apply this knowledge into the clinical situation. However, there does not seem to be any integration between the various disciplines. In addition subjects like Pathology, Pharmacology and Microbiology are often taught in isolation with the students seldom appreciating the importance of these subjects with respect to their needs later in their clinical career.

The curriculum of undergraduate medical students and dental students at BP Koirala Institute of Health Sciences (BPKIHS), Dharan is need based, integrated, community oriented, partially problem based and has incorporated student centered education with early patient contact in line with innovative education programmes as epitomized in the Edinburgh Declaration of 1988. Recently, effective methods for more active participation and interaction of students, problem based learning and various clinical exercises has been added to the text of Pharmacology.

Practical lesions are an important part of Pharmacology curricula of various undergraduate courses, such as medicine, nursing, sciences and pharmacy. *In vitro* and *in vivo* animal experiments have been widely used in the practical lessons to help students gaining hands- on skills of Pharmacological experiments, and more importantly, reinforcing their knowledge learned from lectures and text-books. Although traditional live animal experiments are invaluable, they do have shortcomings, and their cost- effectiveness has been questioned. Apart from being time consuming, animal experiments can only test a limited number of drugs at a given period of time and misleading results often to the extent of 95.0% failure rates of tested compounds in human beings.[3-7] Furthermore, animal experiments, in particular whole animal studies, are often labour-intensive and costly.[7,8] Previous evidence has shown that this innovative educational technique like computing programs and simulated clinical cases, either as an adjunct to the traditional teaching methods such as lectures or as a sole teaching tool for distance education or home studies, facilitates students' learning and improves overall study outcomes in Pharmacology.[8-12]

However, human trials are ultimately the most valid method since these can reveal the effect of drug and it's processing in human body.[4]

The aim of the present study was to see the impact of sequential running of animal experimentation and simulated clinical trial in humans to observe the effect of analgesics on the understanding of Pharmacology by the medical students. At the same time we coveted to acclimatize students to the methodology of Phase-I clinical trial. This corollary was appraised from the student's response to the semi structured questionnaire farmed by the faculty members of department of Pharmacology at BP Koirala Institute of Health Sciences.

MATERIALS AND METHODS

A semi structured questionnaire was designed to obtain the students view on the evaluation of analgesic activity in laboratory animals and in human volunteers. These exercises were run in alternate modes and were included in the curriculum of 2nd year MBBS and BDS students of the BP Koirala Institute of Health Sciences at Dharan, Nepal. The identity of the responders' was kept anonymous. There were a total of ten items in the framed questionnaire, which was divided into two sections A and B each containing five items. Section A was framed to assess the feedback on the Evaluation of analgesic activity in laboratory animals and section B dealt with evaluation of analgesic in human volunteers. These sections dealt with predilection, methodology, understanding, interest and the inclination for addition of more such exercises. Apart from these items there were interrogations about which exercise was more explicable, motivating, interactive and the response to sequential animal experiments and SCT of these exercises from the students point of view. The responses were tallied on the Likert system of scoring. The feedback from the students was obtained at the end of these exercises by unbiased observers to overcome inhibitions of the students.

The study was approved by Institutional Ethical Committee for animals and humans.

Evaluation of analgesic drugs in animals: In this exercise the analgesic activity of the drug was studies in response to physical thermal and chemical stimuli. The physical stimulus was applied in the form of tail clip. The time taken by the animal to dislodge clip from the tail was taken as a parameter for analgesic activity. The thermal stimulus was studied by hot plate method. A cut off time of 30 second was allowed to avoid any thermal injury to the paws of mice. The increase in the reaction time was taken as a measure for analgesic activity. Writhing test was employed to study the response of drug to chemical stimuli. The number of writhing was counted for a period of 10 minutes after administration of the drug. Three observations were made pretreatment and post treatment for 45 minutes at an interval of 15 minutes in each set of experiment. All the annotations were compared against a control animal receiving distilled water.

Evaluation of analgesic drugs on human volunteers: Before commencing with this experiment a written informed consent was taken from the subjects. The increase in produced pain threshold was taken as an indicator of analgesic activity of the drug. The pain was produced by pressing a cork on an inflated cuff of sphygmomanometer. The pressure was gradually raised in steps of 10 mm Hg for 10 seconds till the time subject experiences perceptible pain. The medical and dental students were assorted into subjects of observer and subject each. The observers and the subjects were randomly selected from the students. The codes of the drugs (paracetamol, Ibuprofen, codeine) and placebo were kept confidential during the practical. Three reading were recorded at an interval of 2 minutes after 45 minutes of oral administration of respective drugs. The observations were compared against the values at baseline i.e. at zero minutes. Simultaneously, pulse rate and pupil size and any adverse events were also recorded. The codes of the drugs were revealed at the end of this exercise to the students.

RESULTS

Of the 164 questionnaire, only 154 students completed questionnaire.

On analysis of section A dealing with evaluation of analgesic activity in animals, it was observed 77.9% students preferred animal experiments, 83.1% students were satisfied with the methodology depicting analgesic activity in animals, 94.2% students could understand the objectives, 95.5% students found animal experiments interesting and 79.2% students wanted introduction of further analogous experiments (Table-1).

On analysis of section B, dealing with the evaluation of analgesic activity in human volunteers, it was perceived 74.5% students were glad to participate as volunteer for these exercises, 56.5% students were pleased to be an observer, 85.1% students were satisfied with the technique demonstrated for evaluation of analgesic activity in humans, 89.6% students found it interesting and 88.9% students desired additional comparable exercise. Table-2 Majority of students i.e. 75.1% favored both exercises for improved understanding of the subject and 66.2% agreed the sequential session of animals

experiment and simulated clinical trialing should be operational in medical teaching. On the contrary, students stumble on SCT by finding it more interesting (74.0%) and willingness for participation as a subject (81.9%).

DISCUSSION

In undergraduate medical education, several institutions are switching over from traditional discipline-based curricula to integrated curricula.[13] Some of the curricular innovations that are commonly adopted by progressive medical institutions are community-based teaching and early clinical exposure (ECE).[14] ECE facilitates integration of basic and clinical sciences and improves students' attitude towards basic sciences.[15] For any system of education to function smoothly, it is said that it should be acceptable to both receiver and provider, this holds true for medical education. The teachers should not only try and innovate teaching learning methodology adopted by them from time to time but should also be a willing partner in introducing newer concepts and methodologies for improving the system of medical education in their respective institutions. However, it is important before advocating any changes that the students perception to the existing system is obtained. Obtaining a feed back from the students is one of the ways to assess the relevance of the innovations and modifications and also to find out if the objectives were correct and understandable by the students.[16-18]

The primary finding of the study on assessing the students response is that sequential sessions of laboratory exercises in animals as well as simulated clinical trial received by undergraduate medical and dental students, regarded their understanding of Pharmacology was enhanced by these exercise. We have used healthy human volunteer's simulated experiments as a major means of practical lessons in Pharmacology, because we believe that hands-on skills on live animal experiments pertinent to a pharmacological laboratory would not alone gratify the clinical proficiency for undergraduate students.[8] Clinical investigation of existing medicines often leads to important advances as physician discover new uses for these drugs. One example is the early beta- blocker, propranolol, which was first introduced for heart problems but was then unexpectedly found to lower blood pressure in patients. So animal experimentation followed by SCT also enhances the knowledge of variation in effects of drugs on animals and humans. The simulated clinical trials which have been introduced in pharmacological teaching and research seem to have a number of advantages over the traditional live animal experiments, being more cost effective, offering more accurate and consistent end results, and also understanding the ethics of medial research on the patients.[9] Furthermore, such exercise reduce the use of animals and their injudicious use, which has been a concern of students and animal rights organizations. These experiments were included in curriculum of undergraduate students and feed back was obtained at the end of these sessions by the unbiased observers. The analysis of feedback established that a majority of students privileged both exercises for a better understanding of the subject and instigation of sequential sessions of animal experiments and SCT. The response for the participation in allied human volunteer experiments was also high.

In conclusion, incorporation of human volunteer experiments along with analogous animal experiments offers more credence for the learning as well as application of Pharmacology. The affixing of these exercises in the undergraduate curriculum can augment the understanding the subject and the decision to obliterate animal experiments completely from the medical education should be reconsidered by the academicians.

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Table-1: Item analysis of section- A dealing with evaluation of analgesics in laboratory animals (n=154)

S. No.	Parameter	Response of the students (%)
1	Liking for the animal experiment	77.9
2	Satisfaction for the methodology employed	83.1
3	Understanding the subject	94.2
4	Making the subject more interesting	95.5
5	Desire for similar experiments	79.2

Table-2: Item analysis of section- B dealing with evaluation of analgesics in human volunteers (n=154)

S. No.	Parameter	Response of the students (%)
1	Volunteering as a subject	74.5
2	Volunteering as a observer	56.5
3	Satisfaction with the methodology	85.1
4	Making the subject more interesting	89.6
5	Participation in analogous experiments	88.9