Context-Based Adr Reporting Training To J-Adrrts: Need Of A Step Forward Towards Medication Safety

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Abstract

Introduction: Detecting, reporting and managing adverse drug reactions (ADRs) is a challenge for Health care professionals as they are insufficiently trained for this task during curriculum. The context-based clinical pharmacovigilance training has proven easy, effective and feasible for its application.

Aim: In this study we assessed the adaptability and competency of a Junior Adverse Drug Event Reporter Trainees (J-ADERTs) to context based learning.

Methodology: The Junior Adverse Drug Event Reporter Trainee (J-ADERTs) team divided in to two groups consist of 70 II MBBS students in each group. One group A was tasked with first didactic lecture followed by demonstration of ADR reporting with structured clinical case and in last step asked to fill and report any case of adverse event from the clinical department where the clinical posting is going on. Another group B was tasked with first didactic lecture followed by last step to fill ADR form and report any case of adverse event. Adaptability was evaluated using feedback questionnaires. Competency of a Junior Adverse Drug Event Reporter Trainee was assessed in reporting ADRs was evaluated using a control report format and questionnaires before and after participation.

Result: Total 140 students from II phase MBBS participated in this task. Study group A showed better results in OSCE score than study group B with mean (17.42 and 16.22 respectively). In our study P value is less than alpha value ($p<0.05$). This rejects our null hypothesis and showing significant difference between the OSCE score of two groups. Group intervened with context-based learning showed statistically significant improvement than non-intervened group.

Conclusion: The students acquired basic, relevant and clinical pharmacovigilance skills and knowledge and they felt that it will be very useful in future.

Keywords: Junior, Adverse Drug Event Reporter, Trainee, ADR report form, pharmacovigilance skill

Introduction

Context-based learning, CBL, refers to the use of real-life and fictitious examples in teaching environments in order to learn through the actual, practical experience with a subject rather than just its mere theoretical parts. In context-based education, authentic situations ('contexts') are used as starting points for learning content matter ('concepts'). In such studies, contexts provide significance and meaning to the concepts taught. The context-based approach has been investigated extensively in the field of science education.[1]

Spontaneous ADR reporting by health care professionals forms the backbone of pharmacovigilance system. However, under-reporting is a major hurdle in achieving goal of

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pharmacovigilance. In order to improve the reporting rate, it is important to improve knowledge, attitude and practice (KAP) of the healthcare professionals regarding pharmacovigilance and its importance.[2] Detecting, reporting and managing adverse drug reactions (ADRs) is a challenge for Health care professionals as they are insufficiently trained for this task during curriculum. The context-based clinical pharmacovigilance training has proven easy, effective, and feasible for its application.

Most of the healthcare professionals recognize to detect and manage ADR but they lack the skills and knowledge to report it.[3] The healthcare students receive almost no education or training on pharmacovigilance and ADR reporting topic as the educational activities that do exist are mainly outdated and lecture based.[4-6] Context-based clinical pharmacovigilance training, such as reporting ADRs in clinical practice [4,7-9] or assessing real ADR reports[10] has proven effective in increasing students' pharmacovigilance skills and knowledge.[4] The context-based clinical pharmacovigilance educational interventions are effective; they often do not accurately reflect the future work experience of medical students, which limits their educational potential. [10, 11] We conducted this study to anlyze the adaptability and competency of Junior Adverse Drug Event Reporter Trainee in a D Y Patil Medical College Kolhapur with the aim to assess the adaptability and competency of a Junior Adverse Drug Event Reporter Trainees (J-ADERTs) to context based learning.

Methodology:

This prospective study was conducted in D Y Patil Medical College and Hospital, Kolhapur, Maharashtra. The II phase MBBS students participated in this task are considered as a Junior Adverse Drug Event Reporter Trainee. Total 140 students showed interest to be part of this task. Study group A was tasked with didactic lecture followed by demonstration and training of filling ADR form with structured clinical case and group B had given task of filling ADR form for structured clinical case directly. Then students were asked to fill and report any case of adverse event independently from the clinical department where the clinical posting was going on. ADR report forms are evaluated using self-prepared and pre-validated OSCE. To assess the effectivity, pre- test and post-test was taken before and after this task. Feedback form was taken from all the students to know student's adaptability with this training. To avoid bias group B also involved in training after this study.

In both groups, Competency was evaluated by assessing Knowledge with the Pre & post test results, skills by the OSCE [12] and Feedbacks were used to assess the Adaptability.

Table 1- competence level of a Junior Adverse Drug Event Reporter Trainees (J-ADERTs) to context based learning

t-Test: Two-Sample Assuming Equal Variances		
	Group A	*Group B*
Mean	17.42857143	16.22857143
Variance	1.060041408	3.135403727
Observations	70	70
Pooled Variance	2.097722567	
Hypothesized Mean Difference	0	
df	138	

t Stat	4.9016381
P(T<=t) one-tail	0.00
t Critical one-tail	1.655970382
P(T<=t) two-tail	0.00
t Critical two-tail	1.977303542

Graph 1- Adaptability of students for context based method of learning
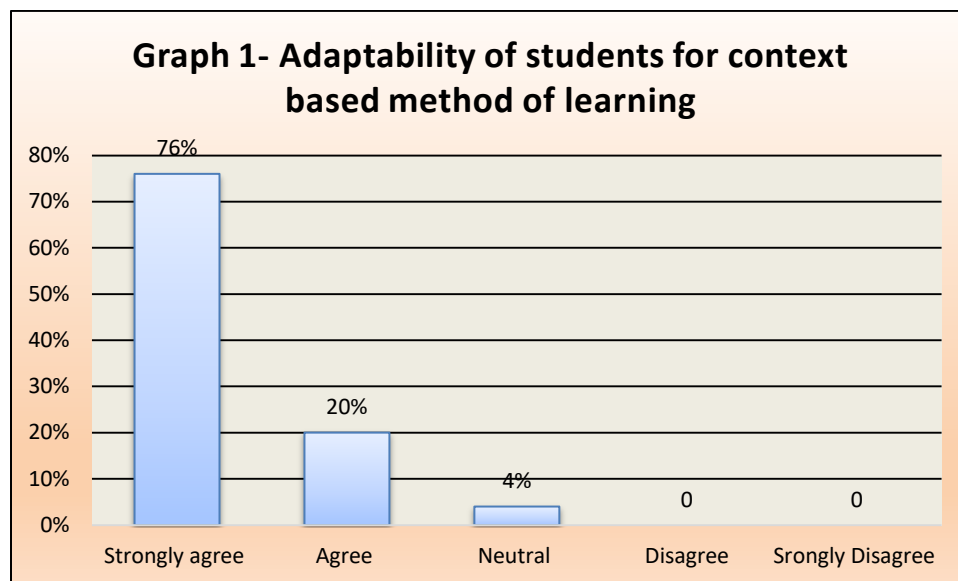
Result And Discussion:

Total 140 students of IInd phase MBBS participated in this task. Study group A showed better results in post-tests & OSCE score than study group B with mean (17.42 and 16.22 respectively). In our study P value is less than alpha value (p<0.05). This rejects our null hypothesis and showing significant difference between the OSCE score of two groups (Table 1). Group A intervened with context-based learning showed statistically significant improvement than non- intervened group B. In feedback 100% J-ADERTs given positive feedback about its benefit in clinical practice. (Graph 1) The students acquired relevant basic and clinical pharmacovigilance knowledge and skills and felt that it will be very useful in future.

Despite a rapidly changing world, outdated pedagogical approaches still persist in science classrooms where the focus is on the rote learning of conceptual knowledge, the application of concepts to routine problems, the treatment of context as secondary to concepts, and the use of practical work to illustrate principles and practices.[13] Improved motivation and learning with CBL was observed by Kuhn et.al. in CBL education by newspaper story problem.[14] Similarly King et.al observed that Context-based approaches offer a new way to engage students in science through more meaningful experiences by situating the learning of science in real-world scenarios.[15] In our study, the J-ADERTs acquired relevant, basic and clinical pharmacovigilance skills and knowledge and acknowledged its usefulness in the future.

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