# A QUESTIONNAIRE BASED STUDY ON KNOWLEDGE AND AWARENESS OF THERAPEUTIC DRUG MONITORING (TDM) AMONG 2<sup>ND</sup>, 3<sup>RD</sup> AND FINAL YEAR MEDICAL STUDENTS OF GOVT. MEDICAL COLLEGE, ANANTHAPURAMU. AP. INDIA

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**ABSTRACT: AIM:** To assess the knowledge and awareness of Therapeutic Drug Monitoring (TDM) among 2nd, 3rd and final year medical students. This study was conducted to assess the level of knowledge and the knowledge gap and awareness of Therapeutic Drug Monitoring (TDM) among 2<sup>nd</sup>, 3rd and final year medical students of Govt. Medical College, Ananthapuramu to conclude regarding importance of Therapeutic drug monitoring in the curriculum of second M.B.B.S. In our study Third year students were considered as final year. It was a Cross-Sectional Questionnaire Based Study where 300 M.B.B.S medical students were surveyed with a questionnaire Proforma after taking an informed consent. 75% of second M.B.B.S students had good level of knowledge about what happens to a drug in the body. 54% of second M.B.B.S students had good knowledge regarding the need to monitor therapeutic level of a drug. Only 2% of second M.B.B.S Students given correct answers about the investigation of TDM. No second M.B.B.S student had the knowledge of instrument used for TDM. 65% of second M.B.B.S. students and 76% of Final M.B.B.S thought that TDM is a new term to them in Pharmacology and affirmed the need for incorporation of TDM in second M.B.B.S curriculum. The present study shows that there is a substantial gap of knowledge about Therapeutic drug monitoring(TDM) in second M.B.B.S students and M.B.B.S final year ,so there is a need of incorporation of Therapeutic drug monitoring(TDM) in second M.B.B.S curriculum.

**KEYWORDS:** TDM, MBBS Students, HPLC, Narrow therapeutic range.

**INTRODUCTION:** Therapeutic drug monitoring (TDM) is defined as measurement of drug levels in the biological fluids usually blood (serum or plasma). It has been carried out in saliva, urine, sweat, tear, fluids, etc. it is carried out for specific drugs at various time intervals in order to maintain a relatively constant concentration of the particular drug in the blood stream and to optimize drug therapy.

The main focus of TDM is on drugs with narrow therapeutic range. Apart from this, it also plays a significant role for drugs having large inter-individual variations; relatively toxic drugs used in concomitant diseases conditions, for escalation of dose, drugs showing wide variation in their metabolism, major organ failure, poisoning cases, failure of therapeutic response, to enhance patient compliance, etc. it is very important in such situations in which the drugs are to be taken on chronic or life-long basis (chronic disease conditions such as bipolar disorder, organ transplant rejection, neurological disorders etc.)

The timing and frequency of blood collection after the medication and correct interpretation of results of analysis and their correlation with clinical features ensures the best therapeutic outcome.<sup>[1]</sup>

**MATERIALS AND METHODS:** This is a detailed structured questionnaire study, involved under graduate medical students (300) of Government Medical College Ananthapuramu, was carried out in the Government Medical College, Ananthapuramu, in September 2014.

In this pilot study 300 students studying in Government Medical College Ananthapuramu, were surveyed with pre-validated questionnaire. The questionnaire was adapted from the previous studies. A few modifications were done in the questionnaire to best fit with reference to university syllabus. The questionnaire included questions on three main categories (general awareness, TDM monitoring instrument, Drugs commonly monitored).

After getting the protocol approved by the Institutional Ethics Committee, a total of 300 students were administered a pre-validated questionnaire containing 20 questions at the end of pharmacology class and they were asked to fill up the questionnaire. The filled questionnaires were collected immediately once they were filled up, on the same day. The questionnaire validation was done by a pilot study on 20 students.

The students were asked to be truthful and unbiased in answering the questions and give remarks and suggestions in the related questions. They were not asked to reveal their identities, in order to make them express themselves freely.<sup>[2,3,4,5]</sup>

**STATISTICS:** Descriptive statistics was used for analysis of data and results were expressed as percentage.

**RESULTS:** Out of total 300 students, 180 were females and 120 were males were involved in our study.

Q. No.	Questions & Options	No. of students answered
1	Are you aware of TDM?	
	Yes	290
	No	10
	Before entering in to 2 <sup>nd</sup> year	20
	In 2 <sup>nd</sup> year	270
2	Do you know about therapeutic index of a drug?	
	YES	285
	NO	15
3	Is there any need to monitor plasma therapeutic level of a drug?	
	YES	250
	NO	50
4	Do you know any investigation that measures the therapeutic level	
	of a drug?	
	YES	210
	NO	90

	What sample, we should send for estimation of	
5	concentration of drug?	
	Saliva	30
	urine	42
	Blood/plasma/serum	280
	sweat	8
	What point of time we should send sample for estimation of	
6	concentration of drug?	138
	At the earliest	
	Random blood sample	150
	frequently based on half-life.	128
7	Is there any facility for TDM available in your institute?	
	yes	
	no	300
8	Is it necessary to have TDM center in our institute?	
	yes	297
	no	3
9	Which of the following group of drugs frequently need TDM?	
	Immunosuppressive	82
	Bronchodilators	165
	Cancer Chemotherapy	120
	Antiepileptic Drugs	188
	Cardio active drugs	152
	Antidepressants	140
	Antibiotics (Antihelmenthic, Antifungal, Anti-malarial Drugs)	144
10	Which common instrument is used for TDM?	
	Spectrophotometer	20
	Fluorimetry	131
	ELISA	22
	Radio immuno assay (RIA):	122
	Thin layer chromatography (TLC):	21
	High performance liquid chromatography (HPLC)	139
	Gas liquid chromatography (GLS)	18
	Fluorescence polarization Immunoassay	52
11	TDM is unnecessary when	
	Clinical outcome is unrelated	55
	Hit and run drugs	168
	Drugs with irreversible action	154
	dosage need not be individualized	28
	Drugs with wide therapeutic range	109
	The pharmacological effects can be clinically quantified	62

12	TDM will be useful in the following situation	
	The drug has a narrow therapeutic range	244
	In case of poisoning	181
	The therapeutic effect cannot be clinically quantified	106
	To check patient compliance	234
	Large individual variability in steady state plasma concentration.	160
13	Major sources of pharmacokinetic variability	
	Compliance	145
	Age	234
	Physiology	78
	Disease	133
	Drug interactions	138
	Environmental influences on drug metabolism	32
	Genetic polymorphisms of drug metabolism	96
14	Which anti microbials need TDM?	
	aminiglycosides	240
	Vancomycin	140
	Teicoplanin	120
15	Which anti-epileptics need TDM?	
	Phenytoin,	
	benzodiazepines,	
	carbamazepine,	
	Valproic acid	
	ethosuximide	
16	Which anti-cancer drugs need TDM?	
	methotrexate	
	cyclosporine	
17	Which cardiac drugs need TDM?	
	procainamide	
	digoxin,	
	lignocaine	
	propranolol	
	quinidine	
19	Which Broncho dilators need TDM?	
	theophyline	
20	Why we have to perform TDM?	
	To check the patient complience	
	In case of poisoning	

Table 1: The views of  $2^{nd}$  year and final year medical students regarding pharmacology [6,7,8,9,10]

**DISCUSSION:** In this study to assess the level of knowledge, a cut off of 60% was taken. That is only in case if 60% or more students give the appropriate response then there exists no knowledge gap. Thus for second M.B.B.S, and Final year M.B.B.S students regarding the knowledge and knowledge gap of Therapeutic drug monitoring, following observations were made - 75% of second M.B.B.S students and only 42% of M.B.B.S final year had good level of knowledge about what happens to a drug in the body. 44% of second M.B.B.S students and 46% of final M.B.B.S had good knowledge regarding therapeutic index of a drug. 54% of second M.B.B.S students and 26% of final M.B.B.S had good knowledge regarding the need to monitor therapeutic level of a drug.

Those questions which were based on Clinical aspects of Therapeutic drug monitoring (TDM). Only 2% of second M.B.B.S Students and 8% of M.B.B.S final year gave correct answer about the investigation of TDM. Only 1% of second M.B.B.S students and 2% of final M.B.B.S gave the correct answer about the sample, its quantity, time for sample collection and its processing for estimation of concentration of a drug for TDM. 13% of second M.B.B.S students and 54% of M.B.B.S final year gave correct answer about TDM (definition of TDM and its implication in clinics). 42% of second M.B.B.S. students and 34% of M.B.B.S final year did not have knowledge regarding the facility for TDM available in their institute. Only 6% of second M.B.B.S students and 78% of M.B.B.S final year answered correctly about the group of drugs that frequently need TDM. No second M.B.B.S student and M.B.B.S final year had the knowledge of instrument used for TDM. 65% of second M.B.B.S. students and 76% of M.B.B.S final year thought that TDM is a new term to them in Pharmacology and affirmed the need for incorporation of TDM in second M.B.B.S practical. From above it is clear that there exists a substantial knowledge gap regarding the theoretical as well as practical knowledge of Therapeutic drug monitoring amongst second M.B.B.S students and M.B.B.S final year both. These observations about the knowledge levels suggest that there is fairly good knowledge about the theoretical aspects of TDM like its meaning amongst the second MBBS students and final year both. Regarding the group of the drugs requiring the TDM only MBBS final year had good knowledge. This may be the result of incorporation of concept of TDM in curriculum. But again not a due weightage is given to discussion of TDM in course or in the textbooks. The level of knowledge about sample ,its quantity, time for sample collection and its processing for estimation of concentration of a drug, TDM team instrument of HPLC was very poor amongst both second MBBS students and final year. The probable reason of this knowledge gap is due to the fact that.

In the second M.B.B.S curriculum recommended by medical council of India, there is no mention of Therapeutic drug monitoring in practical either of second MBBS or final MBBS. To bridge this knowledge gap, we suggests the incorporation of Therapeutic drug monitoring in the practical of second M.B.B.S and increasing the weight age given to TDM in theory of second MBBS. Some of our recommendations of Therapeutic drug monitoring for the incorporation in second M.B.B.S curriculum are- Topics to be incorporated in practical-1. Visit to TDM laboratory. 2. Method of collection of sample. 3. Identification of various parts of High Performance Liquid Chromatography (H.P.L.C.). 4. Therapeutic problems based on concept of TDM. The space required for this incorporation can be provided by deleting some of the pharmacy practical's which have lost their relevance in the modern medical science Topics to be covered in theory- 1. Definition 2. Background 3. Role of Therapeutic drug monitoring (TDM) in safe drug treatment 4. High Performance Liquid Chromatography (H.P.L.C.) 5. TDM team and its functioning. The same knowledge is carried forward by the student to the final year where resensitization can be done in Medicine and clinical posting hence by the time student

enters the final year he or she is well versed with the concept of TDM and its practical implications for the benefit of the patients.

**CONCLUSION:** The present study concludes that there is a substantial gap of knowledge of Therapeutic drug monitoring (TDM) in second M.B.B.S students and M.B.B.S final year, so there is a need of incorporation of Therapeutic drug monitoring(TDM) in practical of second M.B.B.S curriculum and there is need to increase the weightage given to TDM in theory.

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