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Original Research Article

A cross sectional knowledge attitude practice study on therapeutic drug monitoring among health care professionals in a tertiary care hospital

Poovizhi Bharathi Rajaduraivelpandian*, Padmaja Udaykumar

Department of Pharmacology, Father Muller Medical College, Mangalore, Karnataka, India

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***Correspondence:**
Dr. Poovizhi Bharathi Rajaduraivelpandian,
Email: poovizhi.bharathi@gmail.com

ABSTRACT

Background: Therapeutic drug monitoring (TDM) is used to optimize drug's therapeutic effect. Aim of this study is to assess the knowledge, attitude and practice of TDM in health care professionals.
Methods: This was a questionnaire-based cross-sectional study. Questionnaires were distributed to 610 nursing staff and 20 lab technicians. Questionnaires had queries on demography, knowledge, attitude and practice. Descriptive statistics and Pearson correlation were used to analyse the data.
Results: Among nurses, 7% had good, 60.9% had fair and 32.2% had poor knowledge of TDM. Among lab technicians 18.2% had good and 81.8% had fair knowledge on TDM. 79.3% of nurses and all lab technicians had favourable attitude towards TDM. Weak positive correlation is seen between knowledge and attitude among nurses. 15.9% of nurses have sent request for TDM on phenytoin, sodium valproate, carbamazepine, methotrexate, lithium, clozapine, risperidone, tigecycline, vancomycin, gentamicin, digoxin and amiodarone. 100% lab technicians have estimated levels of methotrexate and lithium drug sample during the last one year.
Conclusions: Though knowledge on indication and pharmacological basis of TDM is lacking among participants, their knowledge on sample collection and sample type is good. They have a positive attitude towards TDM. Nurses have requested TDM for only 12 drugs. TDM of only two drugs was done by lab technicians. Future training should focus on pharmacological basis, selection of appropriate drug candidate and indication for TDM service. TDM service should be made available in all tertiary care institutions.

Keywords: Adverse drug reaction, Cost benefit ratio, Lab technicians, Nurses, Therapeutic index

INTRODUCTION

Precision medicine for patient management is achieved by many tools including Therapeutic drug monitoring (TDM).[1] Medication dosage for an individual is tailored based on characteristic of the patient, properties of drug and drug concentration in blood. TDM is essential in pharmacotherapy of neuropsychiatry patients because of wide interindividual variation in pharmacokinetics. The variation is augmented by extremes of age, coexistent disease, concomitant medication and genetic defect.

TDM is required when a particular drug therapy is substituted from one pharmaceutical preparation to other, as it modifies the absorption pattern and consequently the drug concentration. By quantifying concentration of drug in patient's blood serum or plasma, TDM guides to titrate drug dosage in an individual to provide the highest drug efficacy with the lowest risk for adverse drug reaction.[2]

In the last four decades in oncology therapy, TDM for 5-fluorouracil has a validated algorithm for dose alteration.[3] TDM is feasible and safe in several Kinase inhibitors

such as imatinib, sunitinib, pazopanib, everolimus, and tamoxifen.[4] Individual exposure of carboplatin in TI-CE regimen is well controlled by TDM.[5] In children TDM for voriconazole is used to individualize the drug dosage.[6] In MDR-TB, fluoroquinolone TDM is useful in predicting the exposure and to minimize the drug resistance.[7]

TDM optimizes anti-TNF agents' therapy in treatment failure cases of inflammatory bowel disease.[8] Pharmacogenetic knowledge is a requisite for effective employment of TDM while administering Flecainide.[9] The role of TDM in the treatment of cardiovascular diseases is to increase the safety index of digoxin and few antiarrhythmic drugs.[10]

TDM is utilized for therapy with valproic acid, phenobarbital, carbamazepine and newer antiepileptic drugs such aseslicarbazepine acetate, zonisamide, felbamate, lacosamide, lamotrigine, gabapentin, levetiracetam, topiramate, pregabalin, perampanel, rufinamide, stiripentol, retigabine, tiagabine and vigabatrin.[11,12] TDM optimizes the efficacy, reduces the adverse drug reaction and cost of health care by individualizing the drug dosage of atypical antipsychotics and antidepressants.[13,14]

Nurses and lab technicians play a significant role in the process of TDM. Nurses play the role of phlebotomist and counselor. And since TDM is done in clinical laboratory, lab technicians must be aware of the rationale, utility and practice of the service. On taking their roles into account the current study is undertaken to assess the knowledge, attitude and practice of health care professionals towards TDM service. This study is aimed to benefit participants to know about their perceptions for TDM and to use them in the near future to improve the patient care.

METHODS

Study area

The study area was Father Muller Medical College, Mangalore, India.

Study population

Health care professionals (both male and female) working in Father Muller Medical College, Mangalore, India will be included in the study.

Sample size

Minimum of 384 participants were expected to participate according to the following calculation.

Estimate a proportion: $\frac{n \geq Z^2\ 1-\frac{\alpha}{2} \times p(1-p)}{d^2}$

alpha (α)=0.05, estimated proportion (p)=0.51, estimated error (d)=0.05.

Convenient sampling technique. Pretested questionnaire-based cross-sectional study will be done. Study was conducted from April to June 2019 for a period of 3 months.

Inclusion criteria

Inclusion criteria were health care professionals who were involved in the study are nurses, lab technicians.

Exclusion criteria

Exclusion criteria were health care professionals who were not willing to get involved in the study.

Study procedure

Questionnaire validation

Two sets of questionnaires were prepared, one set each for nurses and lab technicians. In the first set there was totally 19 questions, among them 9 were used to assess the knowledge, 4 were used to assess the attitude and 6 were used to assess the practice of TDM service. In the second set of questionnaires for lab technicians there were 10 questions, among which 6 were to assess the knowledge, 1to assess the attitude and 3 were used to assess the practice of TDM service. The credibility of the questionnaire was assessed by validation. Validation was done by doctors from psychiatry department, biochemistry department, community medicine department, and radiation oncology department.

Approval

The protocol was approved by the scientific committee, Father Muller research center.

Enrollment and data collection

Permission was sought from the administrator, Father Muller medical college hospital, and chief nursing officer Sir Janet D'Souza. Before distributing the questionnaire, study participants were completely explained about the importance of this study and by what ways it will benefit the society. A written informed consent was obtained from all the participants. 609 questionnaires were distributed to four batches of nursing staff on four days during their training programme. A time period of 15 minutes was allotted for them to answer the questionnaire. Later their queries regarding TDM were discussed and answered.

The second set of 20 questionnaires containing 10 questions each was distributed to 21 biochemistry lab technicians. They were informed about the study and they were given one day time to respond to the questions. Data

collected was entered in an excel sheet for statistical analysis.

Statistical analysis

Frequency and percentage were used for categorical variables, mean and standard deviation were used for continuous variable and Pearson correlation was used to find relationship between variables.

RESULTS

Altogether the response rate percentage was 97.6%. Response rate among nurses was 99.1%. Response rate among lab technicians was 52.3%.

Demographic

Demographic details of nursing staff and the lab technicians are represented in (Table 1 and 2) respectively. 49.6% of nursing staff and 36.6% of lab technicians fall under the age group 20 to 24 years. 68% of nursing staff and 36.3% of lab technicians falls under 0 to 3 years of work experience.

Knowledge

7% of nurses had good knowledge on TDM, 60.9 % of nurses had fair knowledge on TDM and 32.2% of nurses had poor knowledge on TDM. 18.2% of lab technicians had good knowledge on TDM. 81.8 % of lab technicians had fair knowledge on TDM. Frequency and percentage of knowledge on TDM among nursing staff and lab technicians are represented in Table 3 and 4 respectively. 76.5% of nursing staff are aware about the association between TDM and adverse drug reaction and 72.6% of nursing staff are aware about the constituent of the TDM team. All the lab technicians have knowledge on constituent of TDM team and samples used in TDM. 81.8% of lab technicians have knowledge on sample collection for TDM.

Attitude

79.3% of nurses had favourable attitude towards TDM and 20.7% of nurses had unfavourable attitude towards TDM. Frequency and percentage of attitude on TDM among nursing staff are represented in (Table 5). 91.7% nursing staff felt that Health care professionals should be trained on the fundamental principles of TDM during their course. 88.9% nursing staff felt that TDM is must in all the hospitals.

All the lab technicians felt that TMD service should be mandatory in all the hospitals. Correlation between knowledge and attitude among nurses towards TDM is mentioned in the (Table 6). weak positive correlation is found between the knowledge and attitude of the nursing staff.

Practice

Among nurses, 58.5% are ready to use TDM unit if it is available in the institution, 13.3% are not willing to use TDM unit if it available in the institution. 22.6% are not very sure about using TDM unit. 22.4% are concerned about taking too many of blood samples for dose change while 20.4% say that TDM can increase the duration of stay in the hospital.

Table 1: Frequency distribution of study participants based on age.

Age in years	Nursing staff		Lab technicians	
	Frequency	Percentage	Frequency	Percentage
20-24	299	49.6	4	36.6
25-29	164	27.2	4	36.6
30-34	41	6.8	1	9.09
34-39	13	2.2	0	0
40-44	8	1.3	0	0
≥45	11	1.8	2	18.1

Table 2: Frequency distribution of study participants based on years of experience.

Years of experience	Nursing staff		Lab technicians	
	Frequency	Percentage	Frequency	Percentage
0-3	410	68	4	36.3
4-6	62	10.3	3	27.2
7-9	12	2	2	18.1
10-12	10	1.7	0	0
≥13	19	3.2	2	18.1

Table 3: Frequency and percentage of knowledge items on TDM among nursing staff.

Knowledge items	Response	Nurses (n=603), N (%)
Knows that TDM is used to optimize drugs therapeutic effect	Correct	165 (27.4)
	Incorrect	404 (67)
	Missing	1 (0.2)
Awareness of association of TDM and incidents of adverse drug reaction (ADR)	Correct	461 (76.5)
	Incorrect	142 (23.5)
	Missing	-
Knows that measured drug concentration is low when patient is fast metabolizer/not compliant	Correct	177 (29.4)
	Incorrect	425 (70.5)
	Missing	1 (0.2)
Awareness that TDM reduces cost benefit ratio	Correct	278 (46.1)
	Incorrect	325 (53.9)
	Missing	-
Awareness about constituent of TDM team	Correct	438 (72.6)
	Incorrect	198 (32.8)
	Missing	-
Awareness about ideal time to get back TDM report	Correct	249 (41.3)
	Incorrect	353 (58.5)
	Missing	1 (0.2)
Familiar about the term narrow therapeutic index	Correct	203 (33.7)
	Incorrect	400 (66.3)
	Missing	-
Knowledge about types of sample used in TDM	Correct	215 (35.7)
	Incorrect	388 (64.3)
	Missing	-
Awareness on timing of sample collection	Correct	341 (56.6)
	Incorrect	260 (43.1)
	Missing	-

Table 4: Frequency and percentage of knowledge items on TDM among lab technicians.

Knowledge items	Response	Lab technicians (n=11), N (%)
Familiar with the use of TDM	Correct	1 (9.1)
	Incorrect	10 (90.9)
	Missing	-
Measured drug concentration is low when patient is fast metabolizer/ not compliant	Correct	6 (54.5)
	Incorrect	5 (45.5)
	Missing	-
Awareness about constituent of TDM team	Correct	11 (100)
	Incorrect	-
	Missing	-
Awareness about ideal time to get back TDM report	Correct	6 (54.5)
	Incorrect	5 (45.5)
	Missing	-
Knowledge about types of sample used in TDM	Correct	11 (100)
	Incorrect	-
	Missing	-
Awareness on timing of sample collection	Correct	9 (81.8)
	Incorrect	2 (18.2)
	Missing	-

Table 5: Frequency and percentage of attitude on TDM among nursing staff.

Attitude items	Response	Nurses (n=603), N (%)
Health care professionals should be trained on the fundamental principles of TDM during their course	Strongly agree	307 (50.9)
	Agree	246 (40.8)
	Uncertain	31 (5.1)
	Disagree	12 (2)
	Strongly disagree	4 (0.7)
Reading article regarding TDM is useful	Strongly agree	224 (37.1)
	Agree	315 (52.2)
	Uncertain	40 (6.6)
	Disagree	16 (2.7)
	Strongly disagree	3 (0.5)
TDM is must in all the hospitals	Strongly agree	242 (40.1)
	Agree	294 (48.8)
	Uncertain	46 (7.6)
	Disagree	14 (2.3)
	Strongly disagree	-
Clinical outcome of patients is improved by TDM service	Strongly agree	195 (32.3)
	Agree	307 (50.9)
	Uncertain	72 (11.9)
	Disagree	20 (3.3)
	Strongly disagree	4 (0.7)

Table 6: Correlation between knowledge and attitude among nurses towards TDM.

Variable	Mean	Standard deviation	R value	P value
Knowledge	4.2620	1.53400	0.207**	<0.001*
Attitude	16.8988	2.57151		

**Correlation is significant at the 0.01 level (2-tailed).

23.4% are concerned that patients might not agree to the TDM process. 19.2% are concerned that TDM might increase the cost. The most common indication for TDM in their practice was narrow therapeutic index in 18.2% response, non-compliance in 15.4% response, prevention of ADRs in 53.4% response and poorly defined clinical end point in 5.1% of response. Drugs requested for TDM by the nursing staff in last one year is represented in (Figure 1). Phenytoin, sodium valproate, carbamazepine, methotrexate, lithium, clozapine, risperidone, tigecycline, vancomycin and gentamicin, digoxin, amiodarone were the drugs for which TDM was requested by 15.9% of the nurses in the last one year. About 8% of nursing staff have given erroneous response.

Percentage of nurses who felt the need for sending samples for TDM in the last one year is shown on (Table 7). 33.7 % of nursing staff have not felt the need for sending samples for TDM.

Lab technicians have received and estimated drug levels for methotrexate and lithium during the last one year. Approximately 21-40 samples were outsourced by them for TDM.

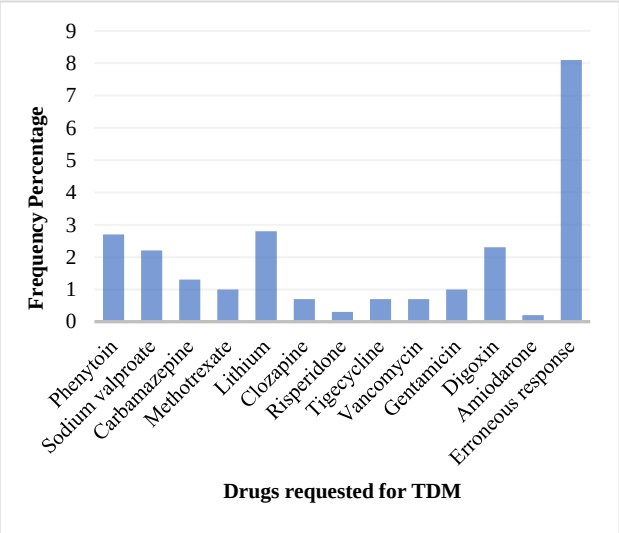

Figure 1: Drugs requested for TDM.

Table 7: Percentage of nurses who felt the need for sending samples for TDM in the last one year.

Nurses	Percentage
Who have not felt the need for sending samples for TDM	33.7
Who felt the need for sending 1-20 samples for TDM	44.9
Who felt the need for sending 21-40 samples for TDM	8
Who felt the need for sending >40 samples for TDM	4.8

Altogether the response rate percentage of study participants was 97.6%. Response rate among nurses= 99.1% and response rate among lab technicians= 52.3%.

DISCUSSION

Percentage of response

614 (97.5%) of health care professionals have responded to the questionnaires which reveals their positive attitude towards our research on TDM.

Demographic details

49.6% of nursing staff and 36.6% of lab technicians fall under the age group 20 to 24 years and 27.2% of nursing staff and 36.6% of lab technicians are of age group 25 to 29 years. 68% of nursing staff and 36.3% of lab technicians falls under 0 to 3 years of work experience. Majority of them are in the early years of their profession.

Knowledge

Questions were framed to assess the knowledge on indications, pharmacokinetic basis, pharmacoeconomic impact, procedures, and type of sample collection in TDM. Only 7% of nurses was found to have a good knowledge on TDM. 32.2% had poor knowledge on TDM. Only 18.2% of lab technicians had good knowledge on TDM.

Among nurses 32.8% know why TDM is used. This is comparatively lesser than 98.43% in the TDM perception study in health-care workers in Nigeria (98.43%).[15] 76.5% know TDM reduces ADR and only 29.4% know it can be used to check non-compliance and identify fast metabolizers. This is because only few know about the fast metabolizers but many are aware of ADR reporting in pharmacovigilance program. 46.1% feel cost benefit ratio can be reduced by TDM but during practice 19% feel TDM increases the cost. A study done in Nebraska shows TDM can reduce hospital stay and markedly increase hospital savings in aminoglycoside induced nephrotoxicity patients.[16] 72.6% knows that they are the part of TDM service. 41.5% are aware that TDM report must be back before next dosing of the concerned drug for dose adjustment. 33.7% are aware of the term Narrow therapeutic index which is slightly higher when compared to a study done in UK to assess knowledge of nurses on pharmacology where only 26.1% got good scoring.[17] 35.7% know what are the samples that should be collected and 56.6% knew that the timing of sample collection varies individually. This shows they are aware of the practical issues during sample collection.

Among lab technicians only 9.1% knew why TDM is used. 54.5% knew that it can be used to check non-compliance and to identify fast metabolizers and ideal time to send TDM report. All knows about members of TDM team and types of sample used in TDM. 81.8% know that the timing of sample collection varies individually. In the study done in Nigeria, all health care workers, viz doctors, nurses and lab technicians were involved in the study but data was calculated as a total and not individually.[15] This drawback is corrected in this study though they are less in number. Lab technicians have adequate knowledge on procedure but inadequate knowledge on aims of TDM.

Attitude

Among nurses 79.3% had favourable attitude towards TDM. All lab technicians felt TDM is must in all the hospitals. A study done in England examined the current practice and perspective of psychiatrists regarding TDM on antipsychotics. The positive expectations and attitudes were in the upper hand when compared to the barriers, negative expectations and attitudes regarding TDM among doctors.[18] Both of these studies show that the attitude towards TDM is very much positive among doctors, nursing staff and lab technicians. There was a weak positive correlation between the knowledge and attitude of the nursing staff. 92.7% of nurses felt they should be trained on fundamental principles of TDM during their course. 89.3% felt reading article on TDM is useful. 88.9% felt TDM is must in all the hospitals. 83.2% felt TDM improves outcome of patient.

Practice

TDM service in India are sorted of two types. Clinical pharmacology department offers TDM service in teaching hospitals and clinical biochemistry department offers drug estimations in private sector.[19] Among nurses, 58.5% are ready to use TDM service if it is available in the institution. In England when study was done on 82.9% of doctors were ready to use TDM service based on availability.[18] Though comparatively less, in our study nurses are ready to use the TDM service, but nurses were concerned about taking too many blood samples (22.4%), increase in length of hospital stay (20.4%), increase in cost of treatment (19.2%) and patient consent (23.4%). But in a TDM study done on antiretroviral treatment, these concerns were found to be resolved. It was found that TDM readily solved 52.1% of medication related

complications and non- typical blood plasma levels during antiretroviral treatment.[20] Hence, appropriate selection of drug candidate for TDM offers greater advantage against the cost.

Anticonvulsants like phenytoin, sodium valproate, carbamazepine; Anticancer drugs like methotrexate, Anti-psychotics and antimanic drugs like lithium, clozapine, risperidone; antimicrobial agents; tigecycline, vancomycin and gentamicin; Cardiovascular drugs like digoxin, amiodarone were the drugs for which TDM was requested by 15.9% of the nurses in the last one year. In a survey conducted in two cancer centers in Jordan, drugs for which TDM was frequently requested were methotrexate, fluorouracil, tacrolimus, cyclosporine, carboplatin, busulfan and theophylline.[21] Among these, TDM is requested only for Methotrexate in our study. 57.7% of nurses felt the need for sending samples for TDM while only 15.9% nurses actually have sent the samples for TDM in the last one year. This is because TDM service is available for only few drugs. TDM of methotrexate and lithium was done in our lab during the last one year. Other 21-40 drug samples were outsourced.

CONCLUSION

Though knowledge on indication and pharmacological basis of TDM is lacking among nurses and lab technicians, their knowledge on sample collection and sample type are good. They have a positive attitude towards TDM. As far as the practice is concerned, they have requested TDM for only 12 drugs, though TDM service is available for many more. TDM of only two drugs was done in the lab. For that reason, future training should focus on pharmacological basis, how to select appropriate drug candidate and indication for TDM service. TDM service of all drugs whose plasma level should be maintained within narrow range should be made available in all tertiary care institutions for the welfare of humanity.

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