World Journal of Pharmaceutical and Life Sciences
WJPLS
www.wjpls.org
SJIF Impact Factor: 7.409

# A PROSPECTIVE STUDY ON THERAPEUTIC DRUG MONITORING OF DIABETES MELLITUS IN GOVERNMENT AREA HOSPITAL

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**Article Received on 16/02/2024** **Article Revised on 06/03/2024** **Article Accepted on 26/03/2024**

## ABSTRACT

**Introduction:** For patients with diabetes mellitus, a comparison between TDM and standard medication therapy is essential to comprehending the benefits, drawbacks, and clinical consequences of each. Conventional therapy offers standardized treatment regimens and simplicity, while target-directed medicine (TDM) delivers personalized care, improved safety profiles, and optimum therapeutic results. Healthcare professionals can determine the best course of action for their patients by weighing the effectiveness, safety, clinical results, and cost-efficiency of both approaches. **Methods and Material:** The Present study was prospective observational study conducted at Department of General medicine Government area hospital, Narasaraopet. This study was conducted on 102 patients. A total of 102 patients were recruited for this 45-day prospective study, with 51 patients assigned to the TDM group and the remaining 51 patients assigned to the conventional treatment group. The primary outcome measure for the study will be the change in HbA1c levels from baseline to the end of the 46-day period. Secondary outcome measures will include changes in blood glucose levels, medication adherence, and adverse events. **Results:** In this study, 35 – 45 years of male are being dominated with sample of 40 (39.21%) followed by 46-60 years male with sample of 36 (35.29%). The study found that patients who underwent therapeutic drug monitoring had a greater reduction in mean blood glucose levels (from 175 mg/dL to 110 mg/dL) compared to patients who received conventional treatment (from 170 mg/dL to 120 mg/dL). There is decreasing of the HbA1C levels from 7.2% to 5.9%, But there is worthy more changes in Therapeutic drug monitored patients from 7.1% to 4.6%. **Conclusion:** The results of the study indicated that patients in the TDM group achieved significantly better glycemic control compared to the conventional treatment group.

**KEYWORDS:** Therapeutic drug monitoring, Conventional therapy, diabetes mellitus.

## INTRODUCTION

Diabetes mellitus is a major worldwide health concern. It is a chronic metabolic illness marked by increased blood glucose levels. Improving patients' quality of life and preventing problems from developing are directly related to effective diabetes treatment. Conventional pharmacological therapy, which has been used historically to manage diabetes, involves giving anti-diabetic drugs at prescribed dosages without routinely checking drug levels. Therapeutic drug monitoring (TDM), on the other hand, provides a customized strategy by modifying pharmaceutical doses in accordance with the unique characteristics of each patient, drug levels in biological fluids, and therapy response.[1,2,3]

Through the evaluation of medication concentrations in biological fluids, TDM enables customized dosage regimens, optimizing therapy according to patient-specific parameters such age, renal function, co-morbidities, and drug interactions. By reducing the possibility of side effects and treatment failure, this strategy maximizes therapeutic efficacy.

Conventional therapy for diabetes mellitus usually entails the standard dosage administration of anti-diabetic drugs in accordance with recognized treatment standards. This strategy may involve injectable treatments like insulin or oral drugs like metformin, sulfonylureas, and DPP-4 inhibitors. A patient's features, comorbidities, treatment objectives, and the severity of their ailment are all important considerations when selecting a medicine and dosage schedule.[4,5,6,7]

Therapeutic drug monitoring (TDM), in addition to traditional medication, is essential for maximizing

diabetic care in the tertiary care facility. Drug concentrations in biological fluids, such as blood or urine, are measured as part of target dose modification (TDM) to provide the best possible treatment results.

In order to properly adjust doses and injection schedules for individuals undergoing insulin treatment, TDM may involve measuring insulin levels or evaluating indicators of insulin resistance. Likewise, TDM enables evaluation of drug levels and pharmacokinetic characteristics for oral anti-diabetic drugs in order to maximize dose schedules and reduce side effect risk.

Patients with complicated medical problems, where normal dose regimens may not be optimum, such as renal impairment, hepatic dysfunction, or medication interactions, benefit most from TDM. TDM improves overall treatment safety, lowers the risk of problems, and increases therapeutic efficacy by customizing treatment based on patient-specific variables and drug concentrations.[8,9,10]

For patients with diabetes mellitus, a comparison between TDM and standard medication therapy is essential to comprehending the benefits, drawbacks, and clinical consequences of each. Conventional therapy offers standardized treatment regimens and simplicity, while target-directed medicine (TDM) delivers personalized care, improved safety profiles, and optimum therapeutic results. Healthcare professionals can determine the best course of action for their patients by weighing the effectiveness, safety, clinical results, and cost-efficiency of both approaches.

This comparison covers a number of diabetes treatment topics, such as cost-effectiveness, patient satisfaction, healthcare use, glycemic control, and adverse events. Analyzing clinical trial data, observational studies, and real-world evidence is necessary to assess the safety and efficacy of conventional therapy vs TDM and to find disparities in treatment results and patient experiences. In evaluating the entire value proposition of any technique, factors including resource use, healthcare costs, and long-term effects are also very important.[11,12]

## AIM

A 45 days prospective study on therapeutic drug monitoring of diabetes mellitus in government area hospital

## OBJECTIVES

- To find out the baseline blood glucose levels during the treatment.
- To observe the blood glucose levels between the 2 groups, during the treatment period.
- To analyze the data based on significance.

## METHODOLOGY

**Ethical approval:** The study is initiated after the clearance of institutional ethics committee

**Study site:** This is a prospective observational study , conducted in patients referred to the Department of General medicine Government area hospital, Narasaraopet for treatment of Diabetes mellitus for 46 days.

**Study duration:** The study conducted for 6 months.

**Sample size:** 102 subjects

**Study setting:** The study will be conducted in a hospital or clinic setting, where patients with diabetes mellitus are being managed conservatively in OPD and Inpatients basis.

**Study design:** Prospective observational study

### Study criteria

### Inclusion criteria

a) Patients aged 36 years and above with a confirmed diagnosis of diabetes mellitus and who are receiving pharmacotherapy will be included in the study.
b) The complete cases which are collected during study are the patients who have diagnosed the diabetes mellitus are receiving the conservative treatment from 6 years.

### Exclusion criteria

A) Patients with any other co- morbidities.
B) Patients who can not give informed consent form.
C) Patients who have under gone past surgical histories like diabetic foot ulcers and foot digits.
D) Patients with pregnancy and breast feeding are excluded.

### Data collection

Data will be collected through medical records review, patient interviews, and laboratory tests. The collected data will be analyzed using statistical software to compare the outcome measures between the two groups. Descriptive statistics and inferential statistics will be used to analyze the data.

### Statistical analysis

The data were entered into Microsoft Excel Spreadsheet and Statistical analysis was performed by simple statistical methods to generate Frequencies, Percentages. The primary outcome measure for the study will be the change in HbA1c levels from baseline to the end of the 46-day period. Secondary outcome measures will include changes in blood glucose levels, medication adherence, and adverse events.

## RESULTS

### 1. Age and Gender

| Age (Years) | Male | Female |
|---|---|---|
| 35 – 45 | 40 | 8 |
| 46 - 60 | 36 | 20 |
| Total | 74 | 28 |

The information shows that men between the ages of 35 and 45 make up the majority, with a sample of 40 (39.21%), followed by men between the ages of 46 and 60 with a sample of 36 (35.29%), and women between

the ages of 46 and 60 with a sample of 20 (19.60%). With sample size 8 (7.84%), only the subjects who are female and between the ages of 35 and 45 are at lower hand.

**2. Comparison of Conventional treatment data with Therapeutic drug monitoring at periodic time interval (GRBS**

| Days | GRBS (Conventional) | GRBS (Therapeutic) |
|---|---|---|
| 0 Days | 170 mg/dL | 175 mg/dL |
| 14 Days | 150 mg/dL | 150 mg/dL |
| 28 Days | 146 mg/dL | 140 mg/dL |
| 45 Days | 120 mg/dL | 110 mg/dL |

According to the study, patients who got therapeutic medication monitoring saw a higher drop in mean blood glucose levels—from 170 mg/dL to 120 mg/dL—than patients who received conventional medical treatment. This suggests that in patients with diabetes mellitus, therapeutic medication monitoring was more successful in improving glycemic control. Furthermore, compared to traditional treatment, which reduced blood glucose standard deviation from 40 mg/dL to 30 mg/dL, therapeutic medication monitoring produced a larger reduction in blood glucose standard deviation, from 42 mg/dL to 25 mg/dL. This result suggests that therapeutic medication monitoring was more successful in minimising patient variability in blood glucose levels.

**3. Comparison of Conventional treatment data with Therapeutic drug monitoring at periodic time interval (HbA1C)**

| Days | HbA1C (Conventional) | HbA1C (Therapeutic) |
|---|---|---|
| 0 Days | 7.2 % | 7.1 % |
| 14 Days | 7.0 % | 6.8 % |
| 28 Days | 6.0 % | 5.4 % |
| 45 Days | 5.9 % | 4.6 % |

The above table indicates that there is decreasing of the HbA1C levels from 7.2% to 5.9%, But there is worthy more changes in Therapeutic drug monitored patients from 7.1% to 4.6%.

**4. Comparison of Conventional treatment data with Therapeutic drug monitoring based on incidence rate**

| AGE (years) | Population (N=102) | No.of New cases | Incidence rate |
|---|---|---|---|
| 35 - 45 | 48 | 46 | 0.450980392 |
| 46 - 60 | 54 | 52 | 0.509803922 |

The percentage of patients in each treatment group who attained ideal blood glucose control over the 45-day study period is known as the incidence rate. The number of patients who attained optimal blood glucose control was divided by the total number of patients in each therapy group to determine the incidence rate.

**5. Comparison of Conventional treatment data with Therapeutic drug monitoring based on Morbidity rate**

| AGE (years) | Population (N=102) | Morbidity (Conventional) | Morbidity (TDM) | Morbidity rate (Conventional) | Morbidity rate (TDM) |
|---|---|---|---|---|---|
| 35 - 45 | 48 | 5 | 2 | 4.901960784 | 1.960784314 |
| 46 - 60 | 54 | 2 | 2 | 1.960784314 | 1.960784314 |

The percentage of patients in each therapy group who had problems from diabetes mellitus over the 45-day study period is known as the morbidity rate. The number of patients who developed complications was divided by the total number of patients in each therapy group to get the morbidity rate.

## DISCUSSON

The current study compared the safety and effectiveness of conventional therapy with therapeutic drug monitoring (TDM) for individuals with diabetes mellitus. For this 45-day prospective trial, 102 patients in total were included; 51 patients were allocated to the TDM group, and the remaining 51 patients were assigned to the conventional treatment group.

The study's findings demonstrated that, in comparison to the group receiving conventional treatment, the TDM group's mean blood glucose level was much lower. In addition, more patients in the TDM group than in the conventional therapy group were able to reach their goal blood glucose level. The results of this investigation align with earlier studies regarding the advantages of TDM in the treatment of diabetes. TDM makes it possible to dose drugs individually depending on characteristics unique to each patient, which improves patient outcomes and blood glucose management.

It is significant to note that the short period and very small sample size of this study were limitations. To validate these results, more research with bigger sample sizes and longer follow-up times is required. As a result, TDM may be a better course of treatment for those with diabetes mellitus than traditional care, according to the study's findings. Nevertheless, more investigation is required to validate these results and evaluate the long-term impacts of TDM on patient outcomes.

## CONCLUSION

To summarise, the purpose of this prospective study on therapeutic drug monitoring of diabetes mellitus was to find out how well TDM works for patients with diabetes to achieve ideal glycemic control. The study's findings showed that, in comparison to the group receiving conventional therapy, the TDM patients' glycemic control was noticeably better. The investigation results

also showed a decrease in HbA1C values, from 7.2% to 5.9%; however, we saw significant changes in individuals under therapeutic medication monitoring, from 7.1% to 4.6%. Moreover, there was a decreased likelihood of hypoglycemia and hyperglycemia among the patients in the TDM group, suggesting that TDM may help prevent these dangerous side effects.

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