



## A STUDY ON INFECTIOUS DISEASE BURDEN AND ASSESSMENT OF ADVERSE DRUG REACTIONS AMONG TYPE- II DIABETES MELLITUS SUBJECTS

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### ABSTRACT:

**Introduction:** People with diabetes are more prone to development of infections. Elevated blood sugar levels enervate the patient's immune system and make the patient vulnerable to infections. Assessing the prescription patterns assure quality medical care by providing feedback to the prescribers.

**Objectives:** To assess the prevalence and the prescription pattern of antibiotics in infections associated with type II diabetes mellitus along with their quality of life. To assess the Adverse Drug Reactions associated with treatment of type-II diabetes mellitus.

**Materials and Methods:** This prospective observational study was conducted in the General Medicine Department of Basaveshwara Medical College Hospital and Research Centre, Chitradurga for a period of 10 months.

**Results:** In this study, a total of 300 diabetic subjects were included, out of which, 192 subjects were having infectious diseases. This study reveals association between infection and diabetes with a prevalence rate of 64%. The most commonly prescribed antibiotic was found to be ceftriaxone. The quality of life of the diabetic subjects associated with infections was found to be displeasing when assessed with a validated questionnaire.

**Conclusion:** The study shows a higher rate of prevalence of infectious disease among diabetic subjects. It is suggested to conduct more studies on this topic.

**Keywords:** Diabetes mellitus; Infectious diseases; Adverse drug reactions; Burden of disease.

### INTRODUCTION

According to studies, the incidence of diabetes have increased surprisingly during 30yrs.<sup>1</sup> In accordance with International Diabetes Federation (IDF), 400 million persons are estimated to have diabetes in 2014 and it is expected to rise up to 590 million by 2035.<sup>2</sup>

People with diabetes are more prone to development of infections. Elevated blood sugar levels enervate the patient's immune system and make the patient susceptible to infections. Furthermore, diabetes related issues like nerve damage and decreased blood flow to the extremities can also increase the chances of infections.<sup>3</sup>

Infection- related mortality is increased among diabetics when compared to non-diabetics, but only with the people having co-morbid cardiovascular diseases.<sup>4</sup>

Antibiotics are the drugs often prescribed for patients in intensive care and surgical departments.<sup>5</sup> Assessing the prescription patterns assure quality medical care by providing feedback to the prescribers.<sup>6</sup> Appropriate antibiotic prescriptions are an important component in quality of life, infection control and cost of efficacy.<sup>4</sup>

It is requisite to accomplish an exploration on infectious disease burden and assessment of adverse drug reactions among type 2 Diabetes

Mellitus (DM) subjects in compliance with above statements.

**MATERIALS AND METHODS**

**Study Site:** The study has been conducted in General Medicine Department, Basaveshwara Medical College Hospital and Research Centre, Chitradurga.

**Study design:** It is a prospective observational study.

**Study period:** The study was conducted for a period of ten months from 2018 to 2019.

**Study subjects:** The study included the subjects who meet the following criteria

**Inclusion Criteria:**

- Both genders were included in the study.
- Both rural and urban subjects were included.
- Subjects having type II DM were included.
- Age group: 20-70 years.

**Exclusion Criteria:**

- Subjects having DM with hypertension were excluded.
- Subjects having DM with TB were excluded.

**Sources of data:**

- Demographics, medication and medical history were collected from the patient profile form and their prescriptions.

**Study procedure:**

The study was initiated after obtaining the ethical clearance from Institutional Ethics Committee (IEC). Subjects who have satisfied the above study criteria have been recruited into the study. All the subjects were explained regarding the study and Informed Consent Form was obtained. The demographic details, medical information, medication data and other relevant information were documented in a pre structured data collection form. A validated questionnaire was used to assess the the quality of life of the subjects.

**Statistical Analysis**

The data were entered in Microsoft Excel sheets and analysis has been done by Social Programme Scientific Software (SPSS) version 24. The data was analyzed by Descriptive methods (Mean).

**RESULTS**

A total of 300 diabetic patients were enrolled into the study. The data of the subjects were analyzed and presented as follows;

**Prevalence according to infections**

Prevalence of infectious conditions among 300 patients were classified as cellulitis (19.0%), diabetic foot ulcer (29.0%), sepsis (1.2%), gangrene (0.6%), asthma (0.6%), pneumonia (8.0%), low RTI (1.3%), upper RTI (0.6%), nephropathy (0.6) and UTI (2.6%). The results are shown in table no.1

**Table 1: Prevalence of Infectious Conditions:**

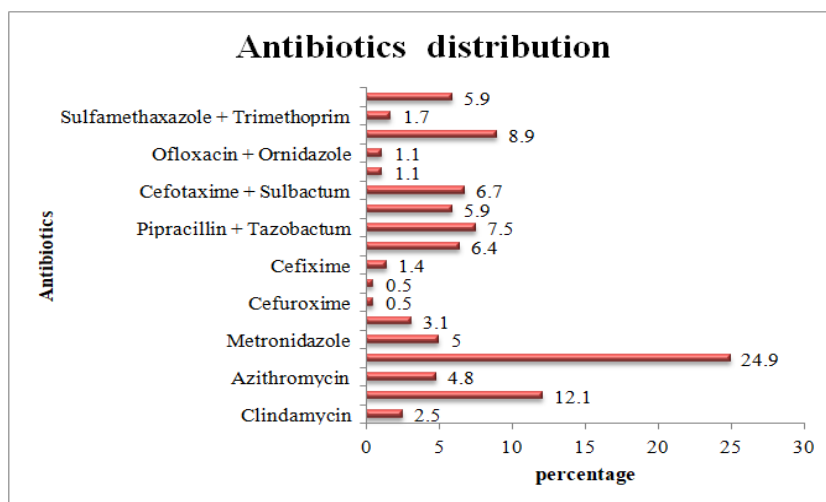
Sr. No.	Infections	Prevalence (%)
1	Cellulitis	19.0
2	Diabetic foot ulcer	29.0
3	Sepsis	1.2
4	Gangrene	0.6
5	Asthma	0.6
6	Pneumonia	8.0
7	Lower RTI	1.3
8	Upper RTI	0.6
9	Nephropathy	0.6
10	UTI	2.6

**Prescription Pattern of antibiotics**

Among the 192 prescriptions, 358 antibiotics were prescribed. The most frequently prescribed antibiotics were ceftriaxone 89 (24.9%) followed by amikacin 43(12.1%) and the least prescribed were cefuroxime 02(0.5%) and ampicillin 02(0.5%). The results are shown in table no.2 and graphically represented in fig.no.2.

**Table 2: Prescription pattern of antibiotics ( n=358)**

Sr. No.	Type of therapy	Drugs	Frequency	Percentage (%)
1	Mono therapy	Clindamycin	09	2.5
		Amikacin	43	12.1
		Azithromycin	17	4.8
		Ceftriaxone	89	24.9
		Metronidazole	18	5.0
		Meropenum	11	3.1
		Cefuroxime	02	0.5
		Ampicillin	02	0.5
		Cefixime	05	1.4
2	Dual therapy	Ceftriaxone + Sulbactum	23	6.4
		Pipracillin + Tazobactum	27	7.5
		Ceftazidime + Tazobactum	21	5.9
		Cefotaxime + Sulbactum	24	6.7
		Cefuroxime + Sulbactum	04	1.1
		Ofloxacin + Ornidazole	04	1.1
		Amoxicillin + Clavunic acid	32	8.9
		Sulfamethaxazole + Trimethoprim	06	1.7
		Ceftriaxone + Tazobactum	21	5.9
<b>TOTAL</b>			<b>358</b>	<b>100</b>



**Figure 2: Prescription pattern of antibiotics**

**Quality of life assessment**

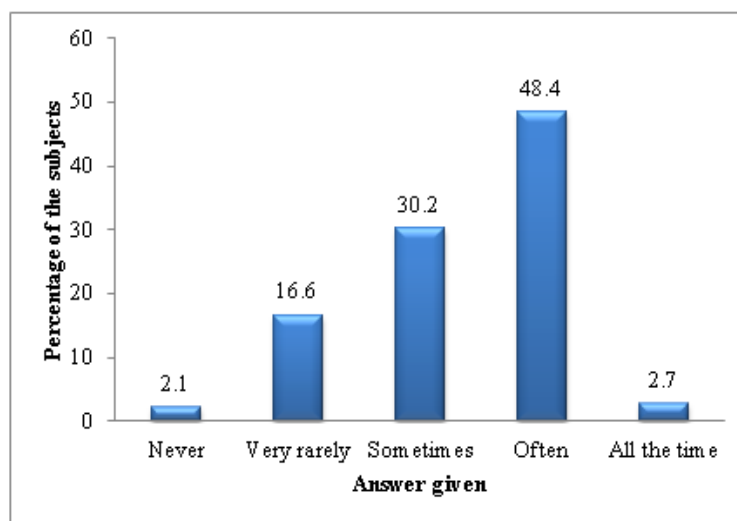
Quality of life of the diabetic patients associated with infections was assessed by a validated questionnaire and the response given by subjects was presented as follows;

**Response to the question: “How often do you worry about whether you will miss work?”**

When the subjects were asked about how much they are worried about missing work due to their health conditions, 93(48.4%) replied that they often do and 04(2.1%) replied that they never. The results are shown in table no.3 and graphically represented in fig no. 3

**Table 3: Response to the question: “How often do you worry about whether you will miss work?”**

Sr. No	Answer given	Frequency	Percentage
1	Never	04	2.1
2	Very rarely	32	16.6
3	Sometimes	58	30.2
4	Often	93	48.4
5	All the time	05	2.7
<b>Total</b>		<b>192</b>	<b>100</b>



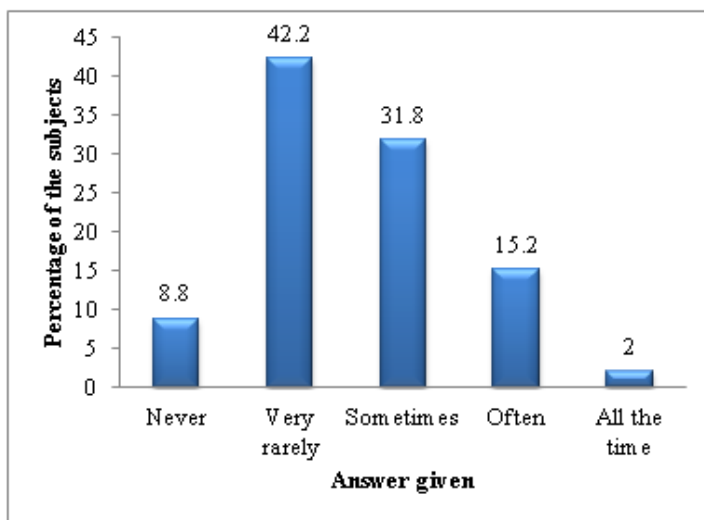
**Figure 3: Response to the question: “How often do you worry about whether you will miss work?”**

**Response to the question: “How often do you have a bad night’s sleep because of diabetes?”**

When the subjects were asked about the impact of diabetes to their sleep, 81(42.2%) replied that they are affected very rarely and 04(2.0%) replied that they are affected all the time. The results are shown in table no.4 and graphically represented in fig no. 4.

**Table 4: Response to the question: “How often do you have a bad night’s sleep because of diabetes?”**

Sr. No	Answer given	Frequency	Percentage
1	Never	17	8.8
2	Very rarely	81	42.2
3	Sometimes	61	31.8
4	Often	29	15.2
5	All the time	04	2.0
<b>Total</b>		<b>192</b>	<b>100</b>



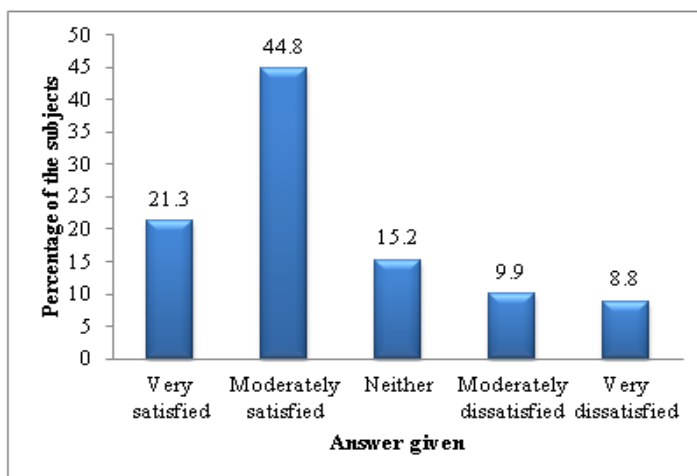
**Figure 4: Response to the question: “How often do you have a bad night’s sleep because of diabetes?”**

**Response to the question: “How satisfied are you with your sex life?”**

When the subjects were asked about their sex life, 86(44.8%) were moderately satisfied and 17(8.8%) were very dissatisfied. The results are shown in table no. 5 and graphically represented in fig no.5

**Table 5: Response to the question: “How satisfied are you with your sex life?”**

Sr. No	Answer given	Frequency	Percentage
1	Very satisfied	41	21.3
2	Moderately satisfied	86	44.8
3	Neither	29	15.2
4	Moderately dissatisfied	19	9.9
5	Very dissatisfied	17	8.8
<b>Total</b>		<b>192</b>	<b>100</b>



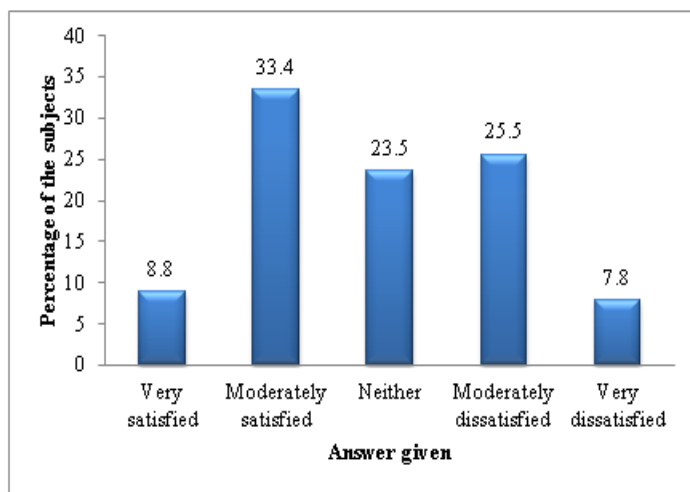
**Figure 5: Response to the question: “How satisfied are you with your sex life?”**

**Response to the question: “How satisfied are you with the burden your diabetes is placing on your family?”**

Among the subjects, 64(33.4%) mentioned that they are moderately satisfied with the burden that their diabetes is placing on their family and 15(7.8%) replied that they are very dissatisfied. The results are shown in table no. 6 and graphically represented in fig no. 6

**Table 6: Response to the question: “How satisfied are you with the burden your diabetes is placing on your family?”**

Sr. No	Answer given	Frequency	Percentage
1	Very satisfied	17	8.8
2	Moderately satisfied	64	33.4
3	Neither	45	23.5
4	Moderately dissatisfied	49	25.5
5	Very dissatisfied	15	7.8
<b>Total</b>		<b>192</b>	<b>100</b>



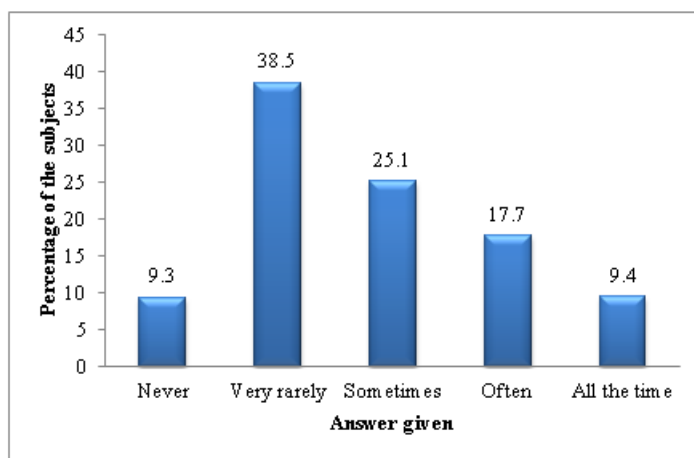
**Figure 6: Response to the question: “How satisfied are you with the burden your diabetes is placing on your family?”**

**Response to the question: “How often do you feel physically ill?”**

74 (38.5%) subjects responded that they feel physically ill very rarely, 18 (9.4%) replied that they never feel ill at all and 18 (9.4%) replied that they feel always ill. The results are shown in table no. 7 and graphically represented in fig. No. 7

**Table 7: Response to the question: “How often do you feel physically ill?”**

Sr. No	Answer given	Frequency	Percentage
1	Never	18	9.4
2	Very rarely	74	38.5
3	Sometimes	48	25.1
4	Often	34	17.7
5	All the time	18	9.4
<b>Total</b>		<b>192</b>	<b>100</b>



**Figure 7: Response to the question: “How often do you feel physically ill?”**

### ADRs Associated with the Treatment

No ADRs were observed during the study time in any of the subjects.

### DISCUSSION

A total of 192 subjects have been found to be suffering from infections out of which the highest incidence rate was of diabetic foot ulcer, followed by cellulitis and pneumonia. Our findings shows that prevalence of various infections associated with type II DM is 0.64 or 64% i.e., 1 in every (4.68 ≈ 5) 5 members likely to be affected by the infections. **Carey I et al.**, conducted a matched cohort study, to assess the risk of infections in type 1 and type 2 DM patients, in which they stated that, patients with diabetes had higher rates for all infections, with the highest incidence rates seen for bone and joint infections, sepsis, and cellulitis. They also reported that the incidence rate of infections in type 2 DM was 1.88.<sup>7</sup>

In our study, out of 192 subjects, 54.8% were on monotherapy and 45.2% on combination therapy. The most frequently prescribed antibiotic was found to be ceftriaxone and the most commonly prescribed anti diabetic drug was a combination of glimepride and metformin (sulfonyl urea and biguanide). **Preeth M et al.**, conducted a similar study which reported that, out of the 110 subjects, 6.3% were on monotherapy and 92.7% on combination therapy. They reported that Cilastin+Imipinem combination was maximally used in the management of infections.<sup>5</sup>

Quality of life of the subjects were analyzed using a validated questionnaire, by which we concluded that majority of the subjects were not much

satisfied by their present condition, which shows that diabetes have affected quality of life of the subjects negatively. **Huang E et al.**, conducted a similar study on quality of life of the diabetic patients, and they concluded that, end- stage complications remains as a great burden in quality of life and they also stated that comprehensive diabetes treatments have a significant negative impact on quality of life.<sup>8</sup>

No ADRs were observed in the study subjects during the study period.

### CONCLUSION

According to the analyzed results and from view of literature, the conclusions made are:

- Our findings shows that prevalence of various infections associated with type 2 DM is 0.64 or 64% i.e., 1 in every (4.68 ≈ 5) 5 members likely to be affected by the infections.
- The most frequently prescribed antibiotic was found to be ceftriaxone.
- Quality of life of the subjects were analyzed using a validated questionnaire, by which we concluded that majority of the subjects were not much satisfied by their present condition, which shows that diabetes have affected quality of life of the subjects negatively.
- No ADRs were observed in the study during the study period.

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