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Research Article

# A Study on Prescription Pattern of Multivitamins in Type-2 Diabetes Mellitus in Tertiary Care Hospital

Anila A.B.<sup>1\*</sup>, Ancy P. Shaji<sup>1</sup>, Sreelekshmi B.S.<sup>1</sup>, Mahesh N.M.<sup>1</sup>, Vishwanath B A<sup>2</sup><sup>1</sup> Department of Pharmacy Practice, Aditya Bangalore Institute of Pharmacy Education and Research Bangalore-560064, Karnataka, India<sup>2</sup> Chairman of Aditya Group of Institution, Bengaluru, India

### ABSTRACT

**Aim of the study:** To study the prescribing pattern of multivitamins in type-2 DM in tertiary care hospitals.

**Materials and methods:** Human ethical approval was taken from human ethical committee, ABIPER Bangalore. The diabetic patients who satisfied the study criteria were enrolled. The patients data's were collected in specially designed documentation form. The collected data's were assessed using descriptive statistics.

**Results:** The study was conducted in 158 patients in which most prescriptions [72.17%] contains water soluble vitamins+minerals. Multivitamins with or without minerals were prescribed for 90[79.76%] and 30[20.24%] days respectively. Multivitamins [100%] were given orally once a day. For indication fatigue [29.11%], water soluble vitamins+minerals were prescribed mostly. Many DM-2 patients were prescribed with water soluble vitamins+minerals which contain vitaminC and calcium carbonate as main constituents. Some of multivitamins doses were showing compliance as per FDA dose recommendations. Tablet formulation containing fat soluble vitamins+minerals[25.31%] were prescribed mostly.

**Conclusions:** Mostly water soluble vitamins+minerals were prescribed for DM-2 patients. Multivitamins with or without minerals were prescribed for 90and30 days respectively. All multivitamins were prescribed in oral route. Mostly water soluble vitamins+minerals were prescribed for fatigue illness associated with DM-2 in which vitamin C and calcium carbonate were the main constituents. Some of the prescribed multivitamin doses were within the FDA recommended dose range. Tablet formulations were frequently prescribed with oral anti-diabetic drugs.

**Keywords:** Multivitamins, Diabetes mellitus, Hypertension, Prescription.

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### \*Address for Correspondence:

Anila A.B., Department of Pharmacy Practice, Aditya Bangalore Institute of Pharmacy Education and Research Bangalore-560064, Karnataka, India

### INTRODUCTION

Diabetes mellitus is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Type-2 diabetes mellitus [DM-2], which results either from the inability of the body to respond properly to the action of insulin produced by the pancreas or insufficient amount of insulin is produced<sup>1</sup>.

Multivitamin is a preparation intended to serve as dietary supplements with vitamins, dietary minerals and other nutritional elements, which having the advantages of increasing energy, improving mental concentration, to prevent nutritional deficiencies and they are incredibly easy

to use<sup>2</sup>. DM-2 is a multifactorial disease that is typically linked to energy metabolism, particularly carbohydrate and fat management in the organism, however, most micronutrients are also involved in some way either as part of the cause or effect of chronic pathology. The consequences and complications of diabetes are the result of an imbalance between free radical formation and their control by natural antioxidants. Thus, those micronutrients that have an antioxidant function are very important in the prevention of the disease and its complications while other non-antioxidant vitamins have also shown a relationship. To resolve this problem we have to administer multivitamin formulations containing antioxidant and non-antioxidant vitamins<sup>3</sup>.

Previous studies have recommended that the multivitamins are required to be administered in their therapeutic doses while prescribing for type-2 diabetic patients. And it is further recommended that the multivitamins along with essential minerals[micronutrients]are to be consumed as a part of the routine diet in diabetic patients<sup>4</sup>.There is no specific guidelines in the treatment of type-2 DM as leafy vegetables and fruits including exercise are commonly recommended along with the diet<sup>5</sup>.

These facts indicate that there is a need to assess the prescribing pattern of multivitamins as alone and in combination with other micronutrients in patients with DM-2.

## MATERIALS AND METHODS

### Duration of Study

- The study conducted for a period of six months

### Site of Study

- Study conducted at tertiary care hospitals[General Hospital, Yelahanka and Aster CMI Hospital, Hebbal]

### Study Design

- A prospective observational study.

### Sources of Data and Materials:

- Patient case sheet
- Medication/treatment chart
- Suitable design documentation form
- Laboratory data report

### Study Criteria:

#### Inclusion Criteria:

- Patients who were diagnosed as suffered from type-2 diabetes mellitus as per ICD 10 criteria.
- Patients who were suffered from type-2 diabetes mellitus with or without hypertension.
- Patients of either gender or aged between 30 and 70 years.

#### Exclusion Criteria:

- Patients who were suffered from type-1 diabetes mellitus.
- Patients who were suffered from type-2 diabetes mellitus with other co-morbidities other than hypertension.
- Patients who were of either gender and aged up to 29 years and above 70 years.

### Method of Data Collection:

- Specifically prepared data collection form

### Procedure:

- The protocol was submitted to Institutional Human Ethical Committee, ABIPER, Bangalore for human ethical approval.
- Those patients who were satisfied the study criteria were enrolled into the study and patient informed consent was obtained.
- The patient's demographic, clinical and medication data were collected into specifically designed data collection form.
- All the data was reviewed from the angle of prescribing pattern of multivitamins, indications, therapeutic regimen with the help of standard references such as WHO guidelines, Micromedex and physician desk reference.

### Analysis of Data:

The collected data was assessed by descriptive statistics.

### Human Ethical Clearance Committee Approval:

- Human ethical clearance committee of ABIPER, Bangalore approved the study and issued a letter of permission to conduct the study.

## RESULTS

### Demographic details of the study patients:

Among the total number of study patients enrolled[158],most of them were male patients[59.50%].Among various age groups, most of the patients suffering from DM-2 from the age group of 60-70years[37.97%].Few male patients were smokers[3.17%] and alcoholic[3.97%]among the enrolled patients. Among the patients enrolled,36[22.78%] patients were suffering from DM-2 alone while 122[77.21%] patients were suffering from DM-2 with hypertension as both are commonly occurring comorbidities.

### Prescription pattern of multivitamins in DM-2 patients:

The multivitamins were found prescribed alone or in combination with micronutrients such as minerals and antioxidants in all the prescriptions. Of these prescriptions, majority[72.17%] contained multivitamins+minerals followed by multivitamins+antioxidants [12.65%], multivitamins with all micronutrients[7.59%] and only multivitamins[7.59%].Among the majority of prescriptions, most of the prescriptions[45.56%] contained water soluble vitamins+minerals followed by fat soluble vitamins+minerals[25.31%].This data indicates that 3/4<sup>th</sup> of the total prescriptions contain multivitamins with minerals while 1/4<sup>th</sup> of the prescriptions contain multivitamins alone and in combination with antioxidants.

**Table 1: Prescription Pattern of Multivitamins With or Without Micronutrients in DM-2 Patients**

Sl.No.	Multivitamins	Number of cases[N=158]	Percentage
1.	Water soluble vitamins	12	07.59%
2.	Fat soluble vitamins	00	00%
3.	Water soluble vitamins+Fat soluble vitamins	00	00%
	Total	12	07.59%
<b>Multivitamins with minerals</b>			
1.	Water soluble vitamins+Minerals	72	45.56%
2.	Fat soluble vitamins+Minerals	40	25.31%
3.	Water soluble vitamins+Fat soluble vitamins+Minerals	02	01.30%
	Total	114	72.17%
<b>Multivitamins with antioxidants</b>			
1.	Water soluble vitamins+Antioxidants	14	08.86%
2.	Fat soluble vitamins+Antioxidants	06	03.79%
3.	Water soluble vitamins+Fat soluble vitamins + Antioxidants	00	00%
	Total	20	12.65%
<b>Multivitamins with all micronutrients</b>			
1.	Water soluble vitamins+Fat soluble vitamins + Antioxidants+Minerals	12	07.59%
	Total	12	07.59%

Notes: 1.DM-2:-Type-2 Diabetes Mellitus. 2. N:-Total number of patients enrolled in study. 3. %:-Percentage.

▪ **Therapeutic regimen of multivitamins:**

In this study all prescribed multivitamins [100%] were given once daily. Multivitamins were not prescribed for 15 days and 60 days in any of the prescription. Water soluble

vitamins, water soluble vitamin+antioxidant and fat soluble vitamin+antioxidant were prescribed for 30 days[20.24%]. All multivitamins which were used along with minerals are prescribed for 90 days[79.76%].All the multivitamins prescribed were administered per oral[100%].

**Table 2: Therapeutic Regimen Of Multivitamins [N=158].**

Sl.No.	Particulars	Number	Percentage
1.	Frequency: OD BID TID	158 - -	100% - -
2.	Duration: 15days: 30days: Water soluble vitamins+Antioxidants Water soluble vitamins Fat soluble vitamins+Antioxidants 60days: 90days: Water soluble vitamins+Minerals Fat soluble vitamins+Minerals Waters soluble vitamins+Fat soluble vitamins+Minerals+Antioxidants Water soluble vitamins+Fat soluble vitamins+Minerals	- - 14 12 06 - 72 40 12 02	- - 08.86% 07.59% 03.79% - 45.56% 25.31% 07.59% 01.30%
3.	Route of administration: Per oral Parenteral	158 -	100% -

Notes: 1.N:-Total number of patients enrolled in study 2. OD:-Once daily. 3. BID:-Twice daily. 4. TID:-Thrice daily.

▪ **Indications for which multivitamins are prescribed among DM-2 patients:**

The chief indications for which multivitamins prescribed among DM-2 patients were found to be dizziness, fatigue and lethargy. Of these multivitamins, majority of prescriptions [72.17%] contained water soluble vitamins+minerals followed by multivitamins+antioxidants [12.65%], multivitamins with all micronutrients[7.59%] and only multivitamins[7.59%] for the above mentioned indications. Among the majority of prescriptions that contained multivitamins and minerals, most of the prescription [45.56%] contained water soluble vitamins+ minerals succeeded by fat soluble vitamins+ minerals [25.31%].For the indication fatigue[29.11%],water soluble vitamins+ minerals were prescribed mostly followed by lethargy [12.02%] and dizziness[04.43%].

▪ **Composition of multivitamins:**

Among water soluble vitamins chromium polynicotinate [200mcg] was present. Chromium polynicotinate was reported for increase insulin sensitivity. Among water soluble vitamins+minerals, vitamin C[150mg] and calcium[20mg] were added in more quantity among others. Among formulation containing water soluble vitamins+fat soluble vitamins+ minerals+ antioxidants, methylcobalamine [1500mcg], alfa-tocoferol [200mg], magnesium oxide [66.32mg] and alfa-lipoic acid[200mg] were more in quantity. Among formulations containing water soluble vitamins+fat soluble vitamins+minerals, vitamin B5[100mg], vitamin E[15mg] and elemental zinc[22mg] was added in more quantity. Among formulation containing fat soluble vitamins and minerals, vitamin D[250IU] and calcium carbonate[500mg] were added in more quantity. No study results are available to comparing with our study.

**Table 3: Compositions of Multivitamins**

Sl.No.	Particulars	Composition[mg:-milligram, mcg:-microgram, IU:-international unit]
1.	Water soluble vitamin Fat soluble vitamins+Minerals+Antioxidants.	Alpha lipoic acid200mg; Beta carotene3mg; Methylcobalamine1500mcg; Zinc oxide24.89mg; Selenious acid0.114mg; Chromium chloride0.152mg; Light magnesium oxide 66.32mg; Magnesium sulphate6.152mg; Alfa-tocoferol200mg.
2.	Fat soluble vitamins+Minerals.	Vitamin D250IU; Calcium carbonate 500mg.
3.	Water soluble vitamins+Minerals.	Riboflavin10mg; Nicacin100mg; Biotin100mcg; Pantothenic acid50mcg; Folic acid1.5mg; Vitamin C150mg; Vitamin B <sub>1</sub> 10mg; Vitamin B <sub>6</sub> 3mg; Vitamin B <sub>12</sub> 15mcg; Elemental zinc15mg; Elemental calcium20mg.
4.	Water soluble vitamins+Antioxidants.	Vitamin C300mg; Beta carotene3mg.
5.	Water soluble vitamins.	Vitamin C152mg; Folic acid1.5mg; Methylcobalamine1500mcg; Inositol100mg; Chromium polynicotinate200mcg; Benfotiamine150mg.
6.	Fat soluble vitamins+Antioxidants.	Tocoferol acetate400mg
7.	Water soluble vitamins+Fat soluble vitamins+Minerals.	Vitamin C75mg, Vitamin B <sub>3</sub> 50mg; Vitamin B <sub>1</sub> 10mg; Vitamin B <sub>2</sub> 10mg; Vitamin B <sub>5</sub> 100mg; Vitamin B <sub>6</sub> 2mg; Vitamin B <sub>12</sub> 7.5mcg; Vitamin D <sub>3</sub> 400IU; Vitamin D <sub>4</sub> 5000IU; Vitamin E15mg; Folic acid1mg; Biotin150mcg; Elemental magnesium18mg; Elemental manganese0.9mg; Elemental copper0.5mg; Elemental zinc22mg; Elemental iron150mcg; Elemental selenium50mcg.

▪ **Prescribing pattern of therapeutic dosage of multivitamin formulations:**

Vitamin B12, Vitamin B6, Vitamin B9, Vitamin D, Vitamin E, magnesium sulphate, calcium carbonate and elemental zinc were in compliance with FDA recommended dose. Vitamin

B2, Vitamin B3, Vitamin B7, Vitamin B5, Vitamin B1, alpha-tocopherol, zinc oxide, selenium acid, chromic chloride, light magnesium oxide, alpha-lipoic acid and beta carotene, elemental-calcium, magnesium, manganese, copper, iron, selenium were in noncompliance with FDA recommended dose.

**Table 4: Prescribing Pattern of Therapeutic Dosage of Multivitamin Formulations**

Sl.No.	Multivitamins	Dose per day[mg: milligram, mcg:-microgram, IU:-international unit]	FDA recommended dose[mg:-milligram, mcg:-microgram, IU:-international unit]	C and NC
1.	Water soluble vitamins:			
	Vitamin B <sub>12</sub>	7.5mcg	6-500mcg	C
	Vitamin B <sub>2</sub>	10mg	1.5-3mg	NC
	Vitamin B <sub>3</sub>	100mg,50mg	14-35mg	NC
	Vitamin B <sub>7</sub>	100mcg,150mcg	300-400mcg	NC
	Vitamin B <sub>5</sub>	150mcg,100mg	5-20mg	NC
	Vitamin B <sub>9</sub>	1mg	400-1000mcg	C
	Vitamin C	150mg,300mg,152mg,75mg	75-2000mg	C
	Vitamin B <sub>1</sub>	10mg,150mg	1.5-3mg	NC
	Vitamin B <sub>6</sub>	3mg,2mg	1.3-100mg	C
2.	Fat soluble vitamins:			
	Alpha-tocopherol	200mg	15-30mg	NC
	Vitamin D	400IU	600-4000IU	C
	Vitamin E	400mg,15mg	15-100mg	C
3.	Minerals:			
	Zinc oxide	24.89mg	50-80mg	NC
	Selenium acid	0.114mg	15-30mcg	NC
	Chromic chloride	0.152mg	200-1000mcg	NC
	Light magnesium oxide	66.32mg	400-800mg	NC
	Magnesium sulphate	6.152mg	1-40mg	C
	Calcium carbonate	500mg	500-1000mg	C
	Elemental zinc	15mg,22mg	8-40mg	C
	Elemental calcium	20mg	1000-2500mg	NC
	Elemental magnesium	18mg	350-420mg	NC
	Elemental manganese	0.9mg	1.8- 11mg	NC
	Elemental copper	0.5mg	900-1000mcg	NC
	Elemental iron	150mcg	8-45mg	NC
	Elemental selenium	50mcg	55-400mcg	NC
4.	Antioxidants:			
	Alpha lipoic acid	200mg	600-1800mg	NC
	Beta carotene	3mg	6-15mg	NC
	Vitamin E	400mg	15-1000mg	C

Notes: 1.FDA:-Food and Drug Administration. 2NC:-Noncompliance 3.C:-Compliance.

▪ **Formulation of multivitamins:**

Majority of the prescription contain multivitamins were in tablet form[50.64%] followed by capsules[49.36%].Among

tablet formulation, fat soluble vitamin minerals[25.31%] were mostly prescribed while in capsule formulation water soluble vitamins+minerals[45.56%] prescribed.

**Table 5: Formulation of Multivitamins**

Sl.No.	Particulars	Number[N=158]	Percentage
1.	Tablets:		
	Water soluble vitamins	12	07.59%
	Water soluble vitamins+Antioxidants	14	08.86%
	Fat soluble vitamins+Minerals	40	25.31%
	Water soluble vitamins+Fat soluble vitamins+Minerals	02	01.31%
	Water soluble vitamins+Fat soluble vitamins+Minerals+Antioxidants	12	07.59%
	Total	80	50.64%
2.	Capsules:		
	Water soluble vitamins+Minerals	72	45.56%
	Fat soluble vitamins+Antioxidants	06	03.79%
	Total	78	49.36%

Notes: 1.N:-Total number of patients enrolled in study. 2. %:-Percentage

## DISCUSSION

We had done our project on the prescription pattern of multivitamins in type-2 diabetic patients because mainly diabetic patients were suffering from nutritional deficiencies. There is a need to study the utilization of micronutrients especially in diabetes mellitus type-2[DM-2] patients.

We had done our study in 173 DM-2 patients with or without hypertension from which 15(8.67%) cases were dropped due to incomplete data. Then we had completed our study in 158 patients in which most of them were male patients (59.50%-[94]) who were at the age group of 30-70 years. Out of 158 patients, 122(77.21%) were suffering from DM-2 with hypertension.

▪ **Prescription pattern of multivitamins with or without micronutrients in DM-2 patients:**

Among 158 prescriptions, multivitamins+minerals were prescribed in 114(72.17%) prescriptions followed by multivitamins+antioxidants, multivitamin+micronutrients and multivitamins. Out of these 114 prescriptions, multivitamins+minerals in that water soluble vitamins+minerals were prescribed more 72(45.56%). There were no previous studies which have assessed such correlation.

▪ **Prescription pattern of anti-diabetic drugs:**

Totally 233 anti-diabetic drugs were prescribed for 158 patients suffering from diabetes mellitus, out of these patients 155(66.52%) were treated with various oral anti-diabetic drugs prescribed alone and in combination. Among oral anti-diabetic drugs, biguanide([42]-18.02%) was mostly prescribed in which metformin[34.33%] was prescribed more as alone and in combination with other anti-diabetic drugs. When comparing with previous studies, metformin is less frequently prescribed in our study<sup>6,7,8</sup>.

▪ **Prescription pattern of multivitamins with DM-2 drugs:**

In our study 40.4% of multivitamins were prescribed with or without micronutrients along with anti-diabetic drugs in DM-2 patients. This value was found to be 18.48% more and 6.2% less when compared to the study conducted by Mayor S et al(2006)<sup>8</sup> and Wysowski DK et al(2015)<sup>6</sup> respectively. Further studies may be needed to

compare prescribing pattern of multivitamin separately in outpatients and inpatients set up for DM-2 patients.

▪ **Analysis of therapeutic regimen of multivitamins with diet among DM-2 patients:**

All multivitamins (100%) were prescribed once daily for oral administration. Water soluble vitamins, water soluble+antioxidants and fat soluble+antioxidants were prescribed for 30 days(20.24%) while multivitamins used along with minerals were for 90 days(79.76%). There were no related studies to compare these results according to our knowledge.

▪ **Analysis of indications for which multivitamins were prescribed among DM-2 patients:**

Multivitamins were prescribed with and without micronutrients to treat dizziness, fatigue and lethargy in DM-2 patients. Our study indicates that the water soluble multivitamins with and without micronutrients were prescribed mostly to treat fatigue and dizziness. However, a study conducted by Martin et al concluded that multivitamins were prescribed as a potential therapy to improve endothelium dysfunction and reduce insulin resistance<sup>9</sup>. These data indicate that the choices of multivitamins are different while treating DM-2 patients. Further studies are required to understand the above topic in more depth.

▪ **Analyzing the composition of prescribed multivitamin formulations:**

Among water soluble vitamins, chromium polynicotinate (200mcg) composition is more which was reported to increase insulin sensitivity. Quantity of vitamin C(150mg) and calcium(20mg) compositions were more in water soluble vitamins+minerals while for fat soluble vitamins+minerals, vitamin E(250IU) and calcium (500mg) were more. Among formulation containing water soluble and fat soluble vitamins with minerals and antioxidants containing methylcobalamine(1500mcg), alpha-tocopherol(200mg), magnesium oxide(66.32mg) and alpha-lipoic acid(200mg) in more quantity while water soluble and fat soluble vitamins with minerals containing vitamin B5(100mg), vitamin E(15mg) and elemental zinc(22mg) in more quantity. No relevant study data was available for comparing these results.

- **To assess the therapeutic dosage of various vitamin formulations with or without minerals as per standard references:**

Some vitamin formulations were in compliance with FDA recommended dose while some were in non-compliance with FDA recommended dose.

- **Assessment of the formulations of multivitamins, which were commonly, prescribed for DM -2 patients:**

In majority of the prescriptions, multivitamins were in tablet form(50.64%) followed by capsule(49.36%).Among tablet formulation, fat soluble vitamin+minerals (25.31%) were mostly prescribed while in capsule formulation water soluble vitamins+minerals(45.56%) were more. There was no head to head study for comparing these results.

## CONCLUSION

- Multivitamins were prescribed alone and in combination with micronutrients along anti-diabetic drugs to treat DM-2 patients in which water soluble vitamins were frequently used.
- DM-2 patients were frequently treated with the combination of human insulin and oral anti-diabetic drugs. Among oral drugs metformin was frequently used.
- All DM-2 patients were prescribed with multivitamins as alone or in combination by oral route once daily. Multivitamins without minerals were prescribed for 1month and with minerals for 3months.
- Multivitamins were prescribed with and without micronutrients to treat dizziness, fatigue and lethargy in DM-2 patients. Our study indicates that the water soluble multivitamins with and without micronutrients were prescribed mostly to treat fatigue and dizziness.
- Many DM-2 patients were prescribed with formulations containing water soluble vitamins+ minerals which contain vitamin C and calcium carbonate as main constituents. Among water soluble vitamins chromium polynicotinate reported to increase insulin sensitivity.
- Some of the prescribed multivitamins doses were within FDA recommended dose range.
- Most of the multivitamins prescribed frequently as alone or in combination with micronutrients was formulated in tablet form followed by capsule.

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## CONFLICT OF INTEREST

There was no conflict of interest among the authors.

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