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# Differentials in dietary intake of macro and micronutrients in patients with type 2 diabetes and foot ulcers: Observations from a pilot study

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SUMMARY

*Background and aim:* The dietary profiles of patients with type 2 diabetes mellitus (T2DM) from Southern India have been infrequently studied. We aimed to study the differences in dietary intake of macro and micronutrients in elderly patients of Type 2 diabetes mellitus (T2DM), with and without foot ulcers.

*Methods:* Elderly patients with T2DM and foot ulcers ($n = 79$; mean age: 60.6 years) and those without foot ulcers ($n = 59$; mean age: 55.0 years) were studied. Biochemical evaluation for measures of glycemia, lipids and albumin were done and staging of foot ulcers was done using Wagner's scale. A 24-hour dietary recall was administered to quantify the mean daily intake (MDI) of macro, micronutrients and trace elements from portion sizes of food items consumed and compared to the recommended dietary allowance (RDA) for Indians aged 55 years and above.

*Results:* In patients with T2DM and foot ulcers, the MDI of carbohydrates, fats and phosphorus were significantly higher whereas the MDI of proteins and micronutrients namely zinc, folic acid, iron and carotene were lower than the RDA. Elderly patients with nephropathy and longer duration of T2DM have higher odds of developing foot ulcers, when compared to patients without foot ulcers.

*Conclusion:* Elderly patients with T2DM and foot ulcers were deficient in dietary intake of proteins and micronutrients inclusive of carotene, folic acid, zinc, and Iron. Clinical care, regular monitoring of dietary intake and appropriate correction of nutritional deficiencies will aid in the management of diabetic foot ulcers.



## 1. Introduction

The prevalence of type 2 diabetes mellitus (T2DM) is increasing in most countries and nearly 79% of patients with T2DM were from low and middle-income countries. An approximate estimate from the International diabetes federation (IDF) states that nearly 463 million adults are affected by diabetes and this burden would rise to 700 million worldwide by the year 2045 [1]. India continues to remain the second largest country, next to China with the largest population of patients with diabetes. On a national scale, the prevalence of diabetes has been increasing even amongst the rural populations of India [2].

The relative risk of micro and macrovascular disorders is 20-fold higher in patients with T2DM when compared to normoglycemic individuals [3]. In patients with T2DM, foot ulceration is a chronic and frequently reported complication with a worldwide prevalence rate of 6.3% [4], and a recurrence rate of 60% in addition to increased risk of foot amputations [5]. Nearly 50% of all diabetes-related

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hospitalizations are attributed to diabetic foot ulcers and its complications. It is estimated that around 10–15% of patients with diabetes may develop foot ulcers at a certain stage of their life and 15% of them undergo amputations of the lower limbs [6].

In India, around 80% of foot ulcers in patients with T2DM are due to peripheral neuropathy and trauma as a result of barefoot walking or ill-fitting footwear, especially in the rural areas. Moreover, about one third of the foot ulcers is attributed to vascular insufficiency [7]. Results from a recent meta-analysis have demonstrated a significantly poorer quality of life in patients with diabetes and foot ulcers [8], which are determined by factors such as the duration of diabetes [9], glycemic status [10] and nutritional status of an individual [11].

Medical nutrition therapy (MNT) plays a pivotal role in the management of hyperglycemia. It is primarily aimed at achievement and maintenance of optimal glycemic control through balanced diet and healthy food choices in accordance with the physiological status and nutritional needs of patients with T2DM [12]. In India, the dietary patterns of populations show wide variability when comparing traditional vegetarian diets with mixed diets, due to its cultural diversity across states [13]. On the other hand, numerous online sources of non-validated information and misconceptions about nutrition in T2DM are widespread in the population. This impedes an effective MNT in a culturally sensitive population [14]. In such scenarios, a comprehensive evaluation of the individual dietary pattern, nutritional and metabolic status of an individual are essential prior to initiation of MNT, particularly in patients with T2DM [15].

The nutritional status of an individual is determined by dietary habits, cultural and environmental influences. It plays a pivotal role in wound healing, especially in patients with diabetes mellitus [11]. There are a few standard nutritional assessment protocols or interventions in clinical practice for evaluation of dietary intake of macro and micronutrients [16]. Amongst those, the 24-h dietary recall is a preferred method in pilot studies for the collection of quantitative data on the dietary pattern of an individual. This method is simple to administer, culturally sensitive, and does not require much time and high cognitive ability from the respondents [17,18].

We hypothesized that elderly patients aged above 55 years with T2DM and foot ulcers would be likely to have an adverse dietary profile that may impact the healing of foot ulcers. There is a lacuna amongst the studies from South India on nutritional deficiencies in elderly patients with T2DM and foot ulcers. Therefore, in this pilot study we aimed to study the differences in macro and micro nutrient intake and to determine the significant factors associated with foot ulcers in patients with T2DM.

## 2. Methodology

This study was conducted at the department of endocrinology, diabetes and metabolism, Christian Medical College, Vellore and was approved by the Institutional review board (IRB number 13337 (RETRO dated 26th of August 2020) for ethics in research studies involving humans. The sample size for this pilot study was calculated using a standard formula with an anticipated standard deviation of the protein intake in patients (T2DM) with and without foot ulcer of at least 9.26 and 10 g respectively. The anticipated difference in means was 4.4, with a power of 80% and an alpha error of 5%, therefore the maximum sample size of 70 individuals was required for each group.

Informed consent was obtained from all participants and confidentiality was maintained for the data obtained from them in accordance to the declaration of Helsinki. Elderly patients with T2DM and foot ulcers (mean age: 60.6 years; $n = 79$) or without foot ulcers (mean age 55.0 years; $n = 59$) who were ambulatory to the hospital for the clinical management of T2DM were included in the study. A detailed clinical assessment included examination for retinopathy, nephropathy and neuropathy. In patients with T2DM & foot ulcers, details on duration of diabetes, ulcer site, size, grade and duration of the ulcers were graded from 0 to 5 based on the Wagner's diabetic foot ulcer classification system [19].The presence of structural abnormalities such as claw/hammer/mallet toe and hallux valgus or prominent metatarsal heads, features of Charcot's foot, amputations and other foot surgery were considered as a foot deformity [20] and treated as per the protocol of standard medical care. Patients with end stage liver disease, renal disease, infectious disease such as tuberculosis and COVID-19, and those unwilling to participate in the study were excluded.

Diabetic peripheral neuropathy was diagnosed and categorized using a clinical examination using a Simmes Weinstein monofilament (10 gm), and biothesiometer more than 15Volts [21]. The Glomerular filtration rate (eGfR) was estimated using the CKD-EPI equation creatinine equation (2009) of the national kidney foundation. Nephropathy was diagnosed when the eGfR was <60 m L/min/1.73 $m^2$. Retinopathy was diagnosed based on changes in fundus as noticed on fundoscopy. Biochemical evaluation for measures of glycemia, lipids, creatinine and urinary micro-albumin were done. Plasma glucose levels were measured by glucose-oxidase method. Glycosylated haemoglobin was estimated by high performance liquid chromatography (D-100, Bio-Rad Clinical Diagnostic Solutions). The serum lipid profile was measured using an enzyme based colorimetric method in an automated analyser (COBAS-B, 101 system, Roche Diagnostics Ltd).

A 24-hour dietary recall was conducted by a nutritionist to quantify the dietary intake of macronutrients namely proteins, carbohydrates, fat and micronutrients namely zinc, iron, calcium and phosphorus. The responses on portion size of foot items consumed per day were quantified for total energy intake inclusive of macro and micro nutrients and compared to the recommended dietary allowance (RDA) and nutritive value of Indian foods stipulated by the National Institute of Nutrition, India [22], and the Indian council of medical research, New Delhi, India.

## 3. Statistical analysis

Data were checked for normality and summarized as Mean ± Standard deviation (SD)/median as appropriate. An independent samples student's *t* test was applied to test for significance amongst the differences of mean values with normal distribution and the Mann Whitney U test was applied for variables with unequal distribution. The data of multiple variables were regularized and a penalized logistic regression analysis was done to determine the factors associated with foot ulcers in patients with T2DM. The *P* value < 0.05 was considered as statistically significant. STATA (Ver 16.0, Stata Corp, USA) was used for data analysis.

## 4. Results

In this study, the mean age and duration of T2DM was significantly higher in patients with foot ulcers when compared to patients without foot ulcers. Amongst biochemical variables, the mean values of total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C) and estimated glomerular filtration rate (eGFR) were significantly lower in patients with T2DM and foot ulcers. However, no significant differences were observed in the mean values of albumin and HbA1c between groups (Table 1). In patients with T2DM and foot ulcers, the prevalence of neuropathy and nephropathy were significantly higher ($n = 34/79$:$P < 0.001$) whereas the

**Table 1**
Anthropometric and clinical profile of patients with T2DM.

| Variables | Patients with T2DM and foot ulcers (n = 79) | Patients with T2DM & without foot ulcers (n = 59) | *P* value |
|---|---|---|---|
| Age (years) | 60.6 ± 10.1 | 55.0 ± 11.1 | < 0.01 |
| Duration of diabetes (years) | 14.2 ± 8.2 | 6.6 ± 8.1 | < 0.01 |
| Body mass index (kg/m$^2$) | 26.8 ± 8.4 | 28.8 ± 7.3 | 0.18 |
| HbA1c (%) | 8.7 ± 2.0 | 9.5 ± 2.5 | 0.10 |
| Total cholesterol (mg/dl) | 130.7 ± 40 | 185 ± 42 | < 0.01 |
| LDL-C (mg/dl) | 83.7 ± 34.3 | 122.6 ± 30 | < 0.01 |
| HDL-C (mg/dl) | 32.0 ± 11 | 44 ± 12 | < 0.001 |
| Triglycerides (mg/dl) | 147.5 ± 70.5 | 145.5 ± 73 | 0.77 |
| Creatinine (mg/dl) | 1.0 ± 0.5 | 0.7 ± 0.3 | < 0.01 |
| Estimated glomerular filtration rate (mL/min/1.73 m$^2$) | 92 ± 61 | 125 ± 52.0 | < 0.01 |
| Serum albumin (g/dL) | 3.8 ± 0.6 | 3.6 ± 0.5 | 0.40 |

Values are presented as Mean ± SD.
*P* value < 0.05: Statistically significant.

prevalence of retinopathy of any degree was significantly lower, when compared to patients with T2DM and without foot ulcers (Fig 1). In patients with T2DM and foot ulcers, a high proportion of unilateral ulceration (n = 36) was noted. The mean size of foot ulcers was 2.2 × 2.1 cm (n = 79) and 45% of patients (n = 36) presented with single site foot ulcer. 27.8% of patients (n = 22) presented with stage 2 ulceration on Wagner's classification. A marginally higher increase in prevalence of Charcot's foot ulcers was noted when compared to amputations and osteomyelitis (Fig 2). Overall, a significantly higher proportion of patients with T2DM (*n* = 67; 84.8%) were on oral antidiabetic drugs (OADs), specifically on mono-pharmacotherapy (*n* = 74; 94%) while about 75% (n = 59) of patients with T2DM were on insulin therapy.

Groupwise, a significant proportion of patients with T2DM and foot ulcers (n = 50; 63.2%) were on insulin therapy, while 48% (n = 38) were on combination therapy of insulin and oral hypoglycemic drugs (OHA). About 22.7% (n = 18) of them patients with foot ulcers were on OHAs alone. In comparison to this, a significantly higher proportion of patients with T2DM and without foot ulcers (n = 56; 81.1%%) were on OHAs and only about 18.8% (n = 13) were on insulin.

### 4.1. Comparison of dietary profiles between groups

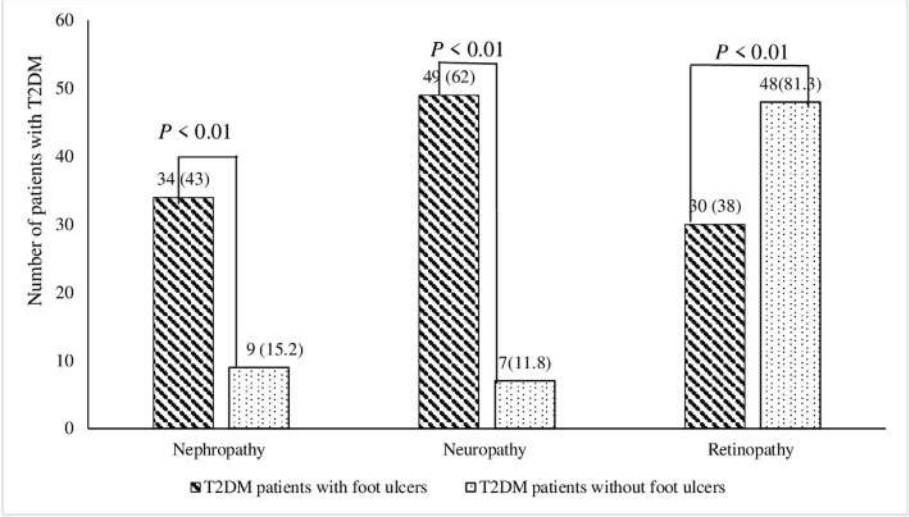
Irrespective of the RDA values, the mean daily intake (MDI) of total energy, carbohydrates, fats and vitamins namely niacin, thiamine and vitamin-C were significantly higher in males with diabetes and without foot ulcers (Table 2). With reference to the RDA, the MDI of carbohydrates and fats were significantly higher whereas the MDI of proteins and micronutrients namely phosphorus, folic acid, vitamin-C, Zinc and niacin were significantly lower in females with T2DM and without foot ulcers (Table 3).

### 4.2. Comparison of dietary profiles based on RDA values for Asian Indians

With reference to the RDA values for an Asian Indian male aged 55 years and above, the MDI of macro nutrients namely carbohydrates and fats were lower. Specifically, MDI of protein and fiber were significantly lower in men with T2DM and foot ulcers in this study. Amongst micronutrients, the MDI of phosphorus, and vitamin-C were significantly higher whereas the dietary intake of calcium was significantly lower, when compared to the RDA in this age group of males. Furthermore, significant deficiencies in dietary intake of folic acid, zinc, riboflavin, carotene and niacin were noted in males with T2DM and foot ulcers.

On the other side, a contrasting pattern was noted in men with T2DM and without foot ulcers. With reference to the RDA values for Asian Indian males aged 55 years and above, the MDI of macronutrients namely carbohydrates, and fats were significantly higher whereas the MDI of protein and dietary fiber were significantly lower. As for the micronutrients, the MDI of folic acid, zinc, riboflavin and carotene were significantly lower when compared to the RDA for Indian males aged 55 years and above (Table 2).

In women with T2DM and foot ulcers, the MDI of carbohydrates, fats and total energy intake were significantly higher, whereas the MDI of protein was significantly lower when compared to the RDA.




Values are presented as actual numbers with % shown in parentheses.

*P* value: < 0.05 statistically significant

**Fig. 1.** Prevalence of microvascular complications in T2DM patients with and without foot ulcers (n, 138).

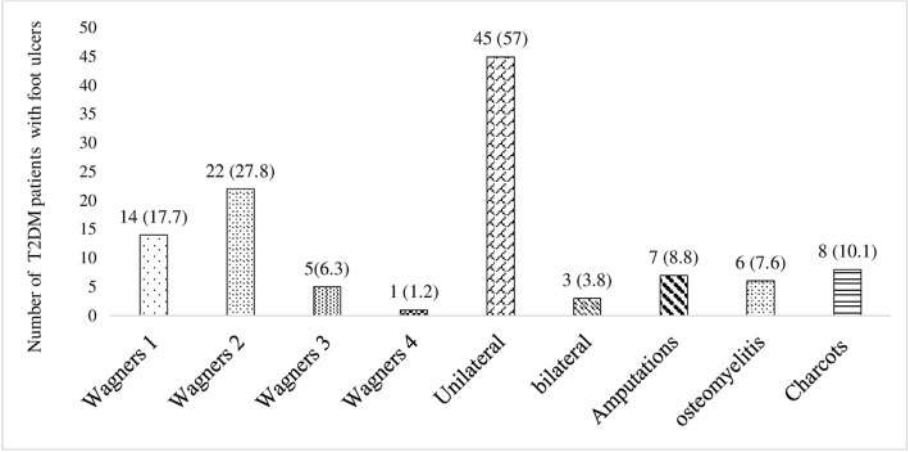



**Fig. 2.** Characteristics of foot ulcers in patients with T2DM (n, 79).

**Table 2**
Groupwise comparison of anthropometric and dietary profile in male patients with T2DM.

| Variables | RDA for Indians | Men with T2DM & foot ulcers (n = 55) | Men with T2DM & without foot ulcers (n = 32) | *P* value |
|---|---|---|---|---|
| Age (years) | NA | 60.8 ± 9.1 | 56.0 ± 10.9 | 0.44 |
| Body mass index (kg/m$^2$) | NA | 26.8 ± 9.4 | 27.2 ± 6.1 | 0.43 |
| Total energy intake (kcal/day) | 1500–1600 | 1462 ± 248.6 | 1872.3 ± 364 | < 0.01 |
| Carbohydrates (gms/day) | 241.6 | 221.1 ± 42.6 | 290.6 ± 52.1 | < 0.01 |
| Protein (gm/day) | 60.4 | 37.8 ± 11 | 42.2 ± 9.7 | 0.47 |
| Fat (gm/day) | 44.7 | 42.8 ± 10.6 | 56.1 ± 15.3 | < 0.01 |
| Calcium (mg/day) | 600 | 628.7 ± 292 | 626.4 ± 233 | 0.97 |
| Phosphorous (mg/day) | 800 | 1264 ± 292 | 1550 ± 367 | 0.12 |
| Thiamine (mg/day) | 1.2 | 1.1 ± 0.4 | 1.2 ± 0.3 | < 0.01 |
| Riboflavin (mg/day) | 1.4 | 0.8 ± 0.3 | 0.7 ± 0.3 | 0.60 |
| Folic acid (μg) | 200 | 171 ± 45 | 173 ± 42.6 | 0.84 |
| Vitamin-C (mg/day) | 40 | 84.8 ± 53.1 | 121.3 ± 67.7 | < 0.05 |
| Zinc (μg/day) | 12 | 8.4 ± 2.8 | 8.6 ± 2.0 | 0.74 |
| Iron (mg/day) | 28 | 17.0 ± 0.5 | 18.8 ± 2.0 | 0.48 |
| Niacin (mg/day) | 16 | 7.2 ± 3.4 | 11 ± 3.6 | < 0.05 |
| Carotene (μg/day) | 4800 | 2091 ± 1178* | 2436.4 ± 817* | 0.64 |
| Fibre (g/day) | 25–30 | 6.3 ± 3.1 | 6.1 ± 2.5 | 0.72 |

Values are presented as Mean ± SD/median (shown in*) NA: Not applicable.
*P* value < 0.05: Statistically significant. *P* values are shown for significant differences between groups, and not for RDA.

**Table 3**
Groupwise comparison of anthropometric and dietary profile in female patients with T2DM.

| Variables | RDA for Indians | Women with T2DM & foot ulcers (n = 24) | Women with T2DM, without foot ulcers (n = 27) | *P* value |
|---|---|---|---|---|
| Age (years) | NA | 60.2 ± 12.4 | 54.0 ± 11.5 | 0.06 |
| Body mass index (kg/m$^2$) | NA | 27.0 ± 6.0 | 30.6 ± 8.2 | 0.09 |
| Total energy intake (kcal/day) | 1500 | 1290 ± 221 | 1628 ± 221.6 | < 0.001 |
| Carbohydrates (gm/day) | 225 | 189.5 ± 33.8 | 250.8 ± 38 | < 0.001 |
| Protein (gm/day) | 56 | 32.1 ± 6.7 | 37.3 ± 8.1 | < 0.05 |
| Fat (gm/day) | 41.6 | 44.3 ± 13.2 | 51.7 ± 10.3 | < 0.05 |
| Calcium (mg/day) | 600 | 574.9 ± 238.9 | 616.6 ± 219.1 | 0.51 |
| Phosphorous (mg/day) | 800 | 1126 ± 254.6 | 1667 ± 350 | < 0.01 |
| Thiamine (mg/day) | 1.2 | 1.0 ± 0.40 | 1.16 ± 0.4 | 0.41 |
| Riboflavin (mg/day) | 1.4 | 0.75 ± 0.32 | 0.80 ± 0.31 | 0.63 |
| Folic acid (μg) | 200 | 136.6 ± 40 | 161.2 ± 38.8 | < 0.05 |
| Vitamin-C (mg/day) | 40 | 73.7 ± 46.8 | 98.8 ± 46 | < 0.05 |
| Zinc (μg/day) | 10 | 7.2 ± 1.9 | 8.4 ± 1.6 | < 0.05 |
| Iron (mg/day) | 21 | 13.8 ± 8.7* | 16.4 ± 12.2* | 0.08 |
| Niacin (mg/day) | 12 | 6.1 ± 3.7 | 8.3 ± 7.8* | < 0.01 |
| Carotene (μg/day) | 4800 | 1892 ± 1247* | 2160.7 ± 821* | 0.64 |
| Fibre (gm/day) | 25–30 | 4.8 ± 2.0 | 6.4 ± 2.2 | 0.61 |

Values are presented as Mean ± SD/median (shown in*).
*P* value < 0.05: Statistically significant. NA: Not applicable.
*P* values are shown for significant differences between groups, and not for RDA.

Amongst micro-nutrients, the MDI of folic acid, Zinc, niacin and carotene were significantly lower with reference to the RDA values for Indian females aged 55 years and above.

In women with T2DM & without foot ulcers, the MDI of carbohydrates, fats were significantly higher whereas the MDI of protein and dietary fiber were significantly lower. Amongst micronutrients, the MDI of phosphorus was two-fold higher. In contrast, the MDI of folic acid, zinc, niacin, carotene and iron were significantly lower when compared to the RDA values (Table 3).

On logistic regression analysis for risk factors associated with foot ulcers in patients with T2DM, factors such as duration of diabetes, presence of nephropathy and prolonged hyperglycemia requiring insulin therapy were derived as significant predictors in the multivariate model. Specifically, the odds of developing a foot ulcer are 6 times higher in middle-aged patients with T2DM and nephropathy. On the other hand, the odds for developing foot ulcers are 7.3 times higher in elderly patients with diabetic nephropathy and in those patients with long term insulin therapy for glycemic control (Table 4).

## 4. Discussion

In this pilot study, the mean age was higher in males than in female patients with T2DM and foot ulcers, although it was not statistically significant. The mean duration of T2DM was higher in patients with foot ulcers which is an important risk factor that influences wound healing. Amongst biochemical variables, the mean values of LDL-C, HDL-C and total cholesterol were significantly lower in patients with foot ulcers when compared to those without foot ulcers. This may be compared to an earlier study from India wherein the mean levels of TC, HDL-C, and LDL-C were significantly lower in patients with T2DM and foot ulcers, than in T2DM patients without ulcers [23]. This feature could be due to the long-term management of dyslipidemia through statins in patients with T2DM.

We used the 24-hour dietary recall method similar to previous studies. A study from Mexico had also used the 24-hour dietary recall method prior to an interventional education program in elderly patients with T2DM [24]. In a pilot study on Spanish and English women, the 24-hour dietary recall method was applied due to its easy format and quick response rate [25].

In the current study, we noted significantly lower dietary intake of micronutrients namely carotene, zinc, folic acid and niacin with reference to recommended dietary allowance (RDA) for Indians. In contrast, we noted an excess intake of Vitamin-C and phosphorus in both groups, irrespective of gender. Vitamin-C plays a significant role in wound healing due to its antioxidant activity, collagen synthesis and cellular apoptosis [26]. However, it is difficult to unravel if there is an association between Vitamin-C intake and wound status, due to the limitations of data from a 24-hour dietary recall in this study.

Protein deficiencies delay wound healing process [27], particularly in patients with diabetes. In this study, the MDI of protein was much lower in patients with foot ulcers when compared to the RDA for Indians. The findings were similar to an earlier study from Pakistan which demonstrated inadequate dietary protein intake in T2DM patients with foot ulcers (66.8 g/day), irrespective of gender [28]. In comparison, the MDI of protein in the current study was 50% lower than the former [28]. This could be attributed to cultural differences in dietary pattern between studies. Gender wise, the MDI of protein, folic acid and iron were significantly lower in both male and female patients with T2DM when compared to the RDA standards for Indians. Furthermore, we noted that the participants consumed carbohydrates as the major source of energy, followed by fats and proteins. These results are in agreement with a previous study in a rural population from south India that reported higher dietary intake of carbohydrates, especially in men [29].

Amongst micro-nutrients deficiencies in dietary intake of carotene, zinc and iron were noted in patients with T2DM with and without foot ulcers, when compared to the RDA for both genders. It is important to note that the deficiencies in dietary intake of carotene, zinc and iron were significantly higher in patients with T2DM and foot ulcers, irrespective of gender. These observations bear similarity to a recent Australian study which reported deficiencies of zinc, vitamin-C, and vitamin A in patients with T2DM and foot ulcers [30]. In the current study, both men and women with T2DM were deficient in dietary intake of zinc similar to the observations of a prospective study in patients with T2DM and foot ulcers from Australia by Pena et al. [31]. Zinc is an essential element for wound healing [32] and its intake from dietary sources needs to be monitored in patients with diabetes and foot ulcers.

Iron is an important dietary micro-nutrient. Anemia due to iron deficiency is common in elderly patients with diabetes. It can impact glycemic control with an increased risk of microvascular complications [33]. Notably, iron deficiency causes alterations in insulin signaling and is associated with oxidative stress and dysfunctional high-density lipoprotein cholesterol (HDL-C) particles [34]. In this study, the mean dietary intake of iron in patients with and without foot ulcers was less than the RDA values for Indians, irrespective of gender. Specifically, iron deficiency in Indian women is highly prevalent [35] and is much concerning in patients with diabetes as it can negatively impact cutaneous wound healing [36]. This needs to be addressed with appropriate dietary interventions and supplementation, especially in female patients with T2DM [37].

In the current study, the intake of dietary fiber was four-fold less than the RDA for Indians in both males and females with diabetes, irrespective of the presence or absence of foot ulcers. This may impact glycemic control, blood lipids, and body weight as evidenced in a meta-analysis of a prospective cohort consisting of 8300 adults with pre-diabetes and diabetes [38]. Uncontrolled hyperglycemia in

**Table 4**
Logistic regression analysis for significant determinants of foot ulcers in patients with T2DM.

| Variable | Univariate Penalized logistic regression | | | Multivariate Penalized logistic regression | | |
|---|---|---|---|---|---|---|
| | OR* | 95% CI | *P* value | OR* | 95% CI | *P* value |
| Insulin therapy | 6.3 | 2.9–13.7 | < 0.01 | 7.3 | 2.16, 25.07 | < 0.01 |
| Age >50 years | 2.55 | 1.28–5.09 | < 0.01 | 2.3 | 0.64–8.46 | 0.19 |
| Gender: Female | 1.92 | 0.96–3.84 | 0.06 | – | – | – |
| LDL-C (mg/dl) | 0.97 | 0.95–0.98 | < 0.001 | – | – | – |
| Duration of DM (years) | 1.20 | 1.12–1.28 | < 0.001 | 1.1 | 1.05–1.23 | < 0.01 |
| HbA1c (%) | 0.87 | 0.73–1.03 | 0.111 | – | – | – |
| Estimated glomerular filtration rate (mL/min/1.73 $m^2$) | 0.99 | 0.98–1.00 | < 0.05 | 1.00 | 0.98–1.01 | 0.55 |
| Creatinine (mg/dl) | 6.12 | 1.78–21.04 | < 0.01 | 1.18 | 0.04–31.05 | 0.92 |
| Presence of nephropathy | 7.91 | 3.23–19.39 | < 0.001 | 5.9 | 1.14–31.40 | < 0.05 |

*P* value < 0.05: Statistically significant. OR: Odds ratio, CI: Confidence Interval.

diabetes mellitus contributes significantly towards the onset of vascular complications of diabetes namely nephropathy [39], neuropathy [10] and retinopathy [40], due to a phenomenon called metabolic memory [41]. In this study, the significant determinants for the risk of foot ulcers in patients with T2DM are duration of diabetes, uncontrolled hyperglycemia requiring insulin therapy and nephropathy. Specifically, in elderly patients with long duration of diabetes and on insulin therapy for the control of hyperglycemia, the odds of developing foot ulcers are seven times higher as shown by logistic regression analysis. On the other hand, in elderly patients with nephropathy and long duration of diabetes, the odds of developing foot ulcers are six times higher after adjusting for confounders such as age and gender. This is higher when compared to a large hospital-based study in patients with T2DM from Saudi Arabia, which reported 4.7 times and a 2.8 times higher odds of developing foot ulcers in patients on insulin therapy and nephropathy respectively. The duration of diabetes more than 10 years was a significant determinant of foot ulcers [42]. Furthermore, the observations of the current study are in agreement with a recent meta-analysis on determinants of foot ulcers in patients with diabetes mellitus. This study has demonstrated factors such as male gender, smoking, duration of diabetes, history of previous foot ulcers, and diabetic peripheral neuropathy to be significantly associated with an increased risk for foot ulcers in patients with diabetes [43].

In summary, this study has shown significant differences in total energy intake inclusive of macro and micro-nutrients in patients with T2DM, with and without foot ulcers. Genderwise, an adverse dietary profile was observed in male patients with T2DM and foot ulcers. The results of the study imply that dietary counselling and continuous monitoring should be included as the standard-of-care in patients with T2DM, particularly in those patients with foot ulcers. This is essential to identify their nutritional needs, particularly that of micronutrients that would aid in the process of wound healing. Data from this study are unbiased as it was obtained from patients who were naive to any form of dietary counselling or interventions. In clinical settings, the factors such as the duration of diabetes, glycemic status and presence of nephropathy needed to be accounted for as important factors that may indicate the risk of foot ulceration in elderly patients with T2DM.

We acknowledge the limitations of the study. Firstly, this is a pilot study which is cross-sectional in design which has applied a 24-hour dietary recall method for data collection. Secondly, a validated food frequency questionnaire was not used, unlike other studies. The data obtained in this study pertain to a semi-rural population of southern India and therefore it cannot be extrapolated to other populations of India. As this study is based on elderly patients with T2DM, the findings cannot be extrapolated to patients with T2DM of other age groups. Furthermore, the staple dietary pattern of participants could not be assessed using a 24-hour dietary recall. Nevertheless, the observations of this pilot study provide baseline data for designing prospective studies using validated questionnaires. Prospective studies in the same population with a larger sample size are essential to decipher the actual burden of nutritional deficiencies in the elderly population with diabetes.

## Statement of authorship

FKJ and RD designed and supervised the study. SR collected the data on dietary intake. BS and RV collected clinical data on foot ulcers. TM analysed and interpreted the data, SA drafted the manuscript and revised it. NT, FKJ and MJ reviewed the manuscript and contributed to the discussion of results. SR, SB, SCN, and RDP contributed to discussion. FKJ is the guarantor for this study.

## Declaration of competing interest

The authors have no conflicts of interest to disclose. This study is independent of financial support from public, private and not-for profit agencies.

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