Study to assess Factors influencing health-related Quality of life in people with Type-1 Diabetes mellitus and their Caregiver Burden in Vijayapura district.

By

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Dissertation submitted to

B.L.D.E. DEEMED TO BE UNIVERSITY
VIJAYAPURA, KARNATAKA

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

In

COMMUNITY MEDICINE

Under the guidance of
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Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapura
2024

DOI 10.5281/zenodo.15493978
https://zenodo.org/records/15493979

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ACKNOWLEDGEMENT

I express my heartfelt gratitude to the Lord Almighty for granting me the strength and wisdom necessary to complete this dissertation, and for accompanying me throughout this remarkable journey.

I am delighted to sincerely thank Dr. Shailaja S Patil, M.D., Professor in the Department of Community Medicine at Shri. B. M. Patil Medical College, Vijayapura, for her outstanding guidance, unwavering support, continuous encouragement, and approachable demeanor have played a crucial role in the completion of this study.

I also wish to extend my heartfelt appreciation to Dr. M C Yadavannavar M.D., Professor & Head of the Department of Community Medicine at Shri. B. M. Patil Medical College, Vijayapura, for his consistent support throughout the preparation of this dissertation.

My gratitude extends to Dr. Aravind V Patil M.S., Principal of Shri. B. M. Patil Medical College, Vijayapura, for permitting me to conduct this study.

I am honored and privileged to extend my sincere respect, regards, and Gratitude to Dr. Rekha Udgiri, M.D., and Dr. M R Gudadinni, M.D., Professors, for their guidance and timely counsel.

I wish to express my heartfelt gratitude to Dr. Praveen Ganganahalli M.D., Dr. Santosh D. Patil M.D., Dr. Chandrika Doddihal M.D., Dr. Tanuja P Pattankar M.D., Associate Professors, and Dr. Sandeep Yankanchi M.D., Dr. Rahmi Hullali, and Dr. Pooja Todalabagi, Assistant Professors, for their invaluable suggestions and support.

I am deeply thankful to Mrs. Vijaya Sorganvi and Mr. Murugesh Math, statisticians, for their valuable assistance in data analysis.

My appreciation also goes to my postgraduate colleagues, Dr.Shanoon Sharaf ali, Dr. Bhoomika N, Dr. Kavimalar T, Dr. Arun P Sasi, Dr. Fyroose E, as well as to my seniors, Dr. Arathy V, Dr. Rupayan Kapri, Dr. Vijay Singh, and Dr. K Priyanga, and juniors, Dr. Shimona.N, Dr Subhajith Giri, Dr Navaratna, Dr Rachel S Daniel, Dr Jafeya R, Dr Shamin E for their unwavering support and well wishes.

I extend my gratitude to all the non-teaching and clerical staff members of the Department of Community Medicine, Shri. B.M. Patil Medical College, Vijayapura, for their cooperation. I also acknowledge the non-teaching staff of RHTC, Ukkali, the Principal, and the staff of all Colleges in Vijayapura for their immense cooperation and support during the data collection process.

I am deeply thankful to my parents, Mr. A.Venkateswara Rao and Mrs. A.Vijaya Lakshmi, and my wife Dr. Bhavya for their constant encouragement, inspiration, and sacrifices, without which I would not have reached where I am today.

Finally, I express my heartfelt appreciation to all the Study participants who Consented to participate and generously contributed their time to provide the necessary information. I also sincerely thank Dr L.H Bidari, pediatric practioner for his contribution, Tertiary care hospital Medicine & paediatric department heads, District hospital staff for their cooperation. This study would not have been possible without their support.

Funding Acknowledgement: The study was funded by the ICMR under PG-Thesis Grant 2022 & intramural funding from BLDE University.

Date:29-6-2024 DR. ANGIREKULA NAGENDRA

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LIST OF ABBREVIATIONS

T1DM	Type 1 Diabetes Mellitus
QOL	Quality of life
DAWN	Diabetes, Attitudes, Wishes and Needs
ZBI	Zarit Burden Interview
WHO	World Health Organization
WBI	Well-Being Index
HRQOL	Health related quality of life
PEDSQL	Pediatric quality of life inventory
EQOL-5D	Euro quality of life 5-dimension questionnaire
WHOQOL-BREF	Quality of life Brief Version
D.T.S. Q	Diabetes treatment satisfaction questionnaire
DSME	Diabetes self-management education
BDI-II	Beck Depression Inventory
MHC	Major histocompatibility complex
HLA	Human leucocyte antigens
TNF	Tumor Necrosis factor
INF	Interferon
OR	Odds Ratio
CI	Confidence Interval
SES	Socio economic status
SPSS	Statistical Package for the Social Sciences.

ABSTRACT

Introduction: Type-1 Diabetes Mellitus (T1DM) presents a significant and growing public health challenge in low- and middle-income countries, particularly among children and adolescents. In 2021, approximately 8.4 million people worldwide had T1DM, with 1.5 million under 20 years old. The prevalence is projected to increase significantly by 2040, especially in low-income countries. In India, the exact rates are hard to determine due to the lack of a comprehensive registry, but T1DM is increasing at an estimated 3-5% per year. Karnataka alone reports a prevalence of 17.9 cases per 100,000 children, highlighting the need for more focused attention and resources for this population.

Managing T1DM is a demanding task requiring strict adherence to daily insulin injections and continuous blood glucose monitoring, which is particularly challenging during adolescence. Poor adherence can lead to severe complications and a lower quality of life. The burden of managing T1DM extends to caregivers, who face significant emotional, financial, and logistical challenges. High levels of stress, financial burden, and lack of adequate support leads to caregivers burden. This study aims to identify factors affecting the quality of life of T1DM patients and their caregivers in the Vijayapura district, Karnataka.

Objectives:

- To assess the health-related Quality of life and well-being and factors influencing the Quality of life among Type 1 Diabetes Mellitus(T1DM) Patients.
- To explore caregivers’ knowledge, attitude, and practice toward T1DM care.
- To assess caregiver burden and provide Health education to caregivers about coping strategies.

Materials & Methodology:

This is a cross-sectional study conducted in the Vijayapura District among T1DM Patients. All patients who met the inclusion criteria were included in the study. In-person interviews were conducted using semi-structured questionnaires to collect socio-demographic data and KAP of caregivers. Additionally, Dawn youth QOL scale, Zarit burden interview & WHO Well-being scales were utilized to assess the Quality of life and well-being of T1DM Patients & their caregiver's burden.

Statistical Analysis:

The data was entered into an Excel spreadsheet and then analyzed using SPSS version 26. Descriptive statistics such as frequencies, percentages, and diagrams were employed to analyze the data. The chi-square test was utilized to examine the statistical associations between the Quality of life, Wellbeing & caregivers' burden and other independent variables. Binary logistic regression was performed for the variables, which were showing statistically significant association.

Results & Conclusion:

We found that most of the Primary caregivers were mothers (75%), and the majority (84%) were nuclear families. A significant proportion of patients resided in rural areas (61%). The predominant age group among T1DM patients was 11-15 years (45%).

Most common clinical characteristics in T1DM patients revealed, with symptoms of frequent urination (41%), giddiness (30%), and abdominal pain (24%). Sleep patterns were reportedly disturbed in 39% of patients, and 29% had irregular bowel and bladder habits.

The majority of patients (78%) had been diagnosed with diabetes for more than a year. In terms of T1 DM control, 55% of patients had poorly controlled HbA1c levels (>7.5%), and 30% required insulin thrice daily.

In the Quality-of-life (Impact of activities domain), Age group and quality of life were statistically associated. Poor QOL was reported more among the age group 16-25 years (56%) compared to 6-15 years. In the domain worries about the diabetes, the Age group & Diabetes duration was found to be statistically associated with the Quality of life (QOL). In the QOL domain of health perception, individuals from nuclear families are having 2.8 times more risk compared to those from joint & three-generation families.

In the Care givers burden, 51% experienced a moderate burden and 33% felt mild burden. Age group of patients showed statistically significant association with the caregiver’s burden. Moderate and severe burden were more among the mothers who are caring for younger age group (6-15 years) Patients, compared to age group of 16-25 years.

WHO well-being screening for T1DM, showed that 51% of the participants have a poor well-being score. In this diabetes duration was found statistically associated with Well-being of the patient.

Our study on T1DM among children and adolescents, along with their caregivers, has provided significant insights into the multifaceted challenges they face. This research highlights the complex interplay of sociodemographic factors, clinical management challenges, caregiver burden, Quality of life & patient well-being in the context of T1DM.

Keywords: T1DM, Quality of life, Well-being, Caregivers burden, Knowledge

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INTRODUCTION:

Type-1 Diabetes Mellitus (T1DM) presents a significant and growing public health challenge in low middle income countries, among children and adolescents.[1] In 2021, there were approximately 8.4 million individuals worldwide with type 1 diabetes, including 1.5 million under 20 years old, 5.4 million aged 20-59, and 1.6 million aged 60 or older. Around 500,000 new cases were diagnosed.[2] One fifth (1.8 million) of these individuals with T1DM were in low-income and lower-middle-income countries. By 2040, the prevalence is projected to increase to 13.5-17.4 million, with the largest relative increase in low-income countries.[2]

The precise incidence and prevalence rates of T1DM in India are difficult to determine due to the absence of a comprehensive nationwide registry and large-scale surveys.[3] T1DM is also on the increase like T2DM, even though not in the same proportion, with a trend of a 3-5% increase per year. India has three new cases of T1DM/10000 children in the age group of 0-14 years.[4] In the state of Karnataka, the prevalence is estimated to be around 17.9 cases per 100,000 children. Given that approximately 40% of India’s population is under 18 years old, the absolute number of T1DM cases is substantial. Despite these significant figures, there is a noticeable lack of focus on this population, highlighting the urgent need for more targeted attention and resources.[4]

Managing T1DM is a relentless and a demanding task. The disease requires strict adherence to daily insulin injections and continuous monitoring of blood glucose levels. This regimen is particularly challenging during adolescence, a period marked by significant physical and emotional changes that often lead to poor adherence to treatment.[5] Poor adherence can increase the risk of severe medical complications, such as diabetic ketoacidosis, retinopathy, and neuropathy, which negatively impact the patient’s quality of life. Research indicates that children from low socioeconomic backgrounds, those recently diagnosed, those diagnosed at an older age, and those with higher HbA1c levels generally experience a poorer quality of life.[6] The chronic nature of T1DM and multipronged management causes significant stress among the patients and their caregivers. Poor health-seeking behavior and social stigma attached to the T1DM further aggravate the behavioral profiles of patients with T1DM.[3]

The burden of managing T1DM extends beyond the patient to their caregivers, who face significant emotional, financial, and logistical challenges. Caregivers are responsible for monitoring blood glucose levels, administering insulin, managing dietary restrictions, and ensuring adherence to the treatment regimen. This constant vigilance is time-consuming and emotionally exhausting, leading to high levels of stress.[7] The financial burden is also substantial, as families must cover the costs of insulin, glucose monitors, test strips, and regular medical visits. In many cases, the cost of managing T1DM can be prohibitively expensive, particularly for families in underdeveloped regions where healthcare resources are limited.[8]

Caregivers of individuals with chronic diseases like T1DM often face significant psychological distress, including anxiety, depression. Without adequate support, caregivers are at risk of severe mental health challenges.[9]

To improve the quality of life for T1DM patients and reduce caregiver burden, a multifaceted approach is necessary. This includes improving access to healthcare services, providing financial assistance for medical expenses, and offering psychological support to both patients and caregivers.[10] Enhanced healthcare access involves ensuring that families have affordable access to insulin, glucose monitors, and other necessary supplies, as well as regular medical check-ups and consultations with healthcare professionals to manage the disease effectively and prevent complications.[11]

Financial assistance can significantly alleviate the economic burden on families. Subsidizing the costs associated with managing T1DM, including insulin and other medical supplies, can make a substantial difference in the lives of patients and their families.[12]

Psychological support is equally important in managing T1DM. Counselling and support services offered by support groups and community initiatives can provide a crucial network of emotional support for both patients and caregivers, helping them navigate the emotional and mental health challenges associated with the condition.[13]

This approach will help manage the disease more effectively and ensure that T1DM patients and their families can lead healthier, happier lives. Addressing the issues faced by caregivers and factors affecting the quality of life of T1DM patients is an important step in the overall management of the disease. However, studies exploring these issues are scarce, particularly in India. This study is an attempt to identify the factors affecting the quality of life among the T1DM population and their caregiver burden in the Vijayapura district, Karnataka.

OBJECTIVES OF THE STUDY

- To assess the health-related Quality of life and well-being and factors influencing the Quality of life among Type1Diabetes Mellitus (T1DM) Patients.
- To explore caregivers’ knowledge, attitude, and practice toward T1DM care.
- To assess caregiver burden and provide Health education to caregivers about coping strategies.

REVIEW OF LITERATURE:

Historical Background of T1DM

Ancient texts from Egypt, India, and Greece describe symptoms resembling diabetes, primarily excessive thirst and urination, historically known as "diabetes mellitus" or "sweet urine." The term was coined by the ancient Greek physician Aretaeus of Cappadocia. For centuries, diabetes was a mysterious and fatal condition with no effective treatment.[14]

However, it wasn't until the late 19th and early 20th centuries that T1DM was recognized as a distinct disease, separate from what is now known as Type 2 diabetes.[15] In the 1970s and 1980s, pivotal research transformed the understanding of T1DM by identifying it as an autoimmune disease. This breakthrough came as scientists discovered that the body's immune system mistakenly attacks and destroys insulin-producing beta cells in the pancreas.[16] George Eisenbarth's work in 1986 was particularly influential, providing a comprehensive model of T1DM pathogenesis that highlighted the autoimmune nature of the disease.[17]

Discovery of Insulin

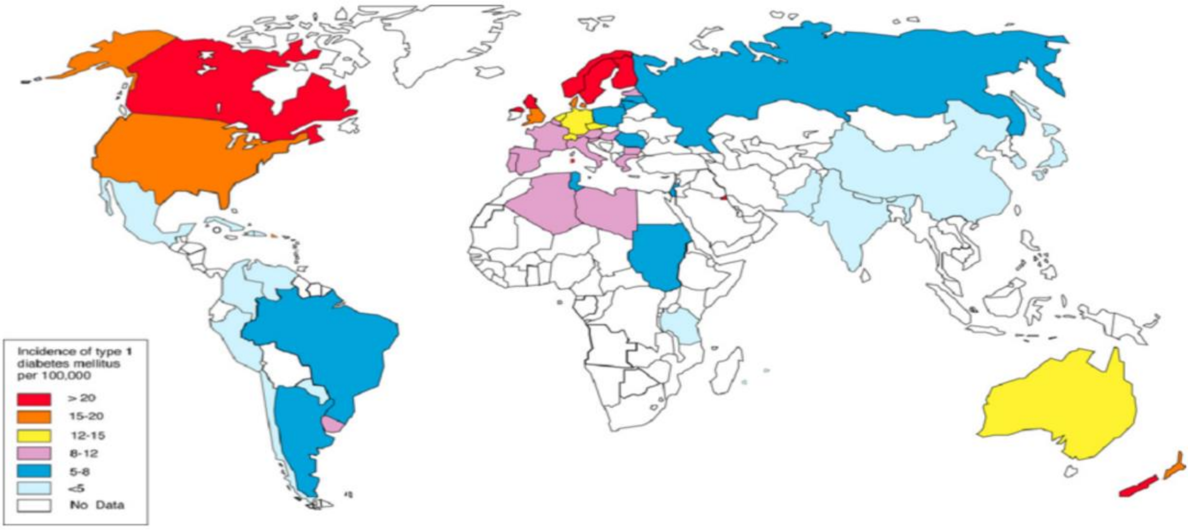
The real breakthrough came in 1921 when Canadian scientists Frederick Banting and Charles Best, with the help of John Macleod and James Collip, discovered insulin[18]. This discovery, awarded the Nobel Prize in Physiology or Medicine in 1923, transformed T1DM from a fatal disease into one that could be managed through insulin injections. The development of insulin therapy revolutionized diabetes care, allowing individuals to live longer and healthier lives.[18]

Geographical distribution of T1DM

Incidence rates of T1DM vary significantly across different populations worldwide, with a striking 350-fold difference observed. This variation often aligns with the distribution of major ethnic groups. Generally, European Caucasian populations, especially those in Northern Europe and regions settled by these groups such as North America, Australia, and New Zealand, exhibit the highest rates of T1DM.[19]

Interestingly, the Baltic countries show significantly lower incidence rates compared to their Scandinavian neighbours, highlighting possible differences in genetics or lifestyle factors. In Asia, T1DM incidence is generally low, except for notably high rates in Kuwait. Middle Eastern countries, including those in North Africa, report intermediate incidence rates. In Central America and the Caribbean, the rates range from low to intermediate, with Puerto Rico and the Virgin Islands being notable exceptions where high incidence rates are recorded. This data underscores the complex interplay of genetic, environmental, and lifestyle factors influencing the global distribution of T1DM.[19]

Figure.1- Worldwide Geographical distribution of T1DM[19]

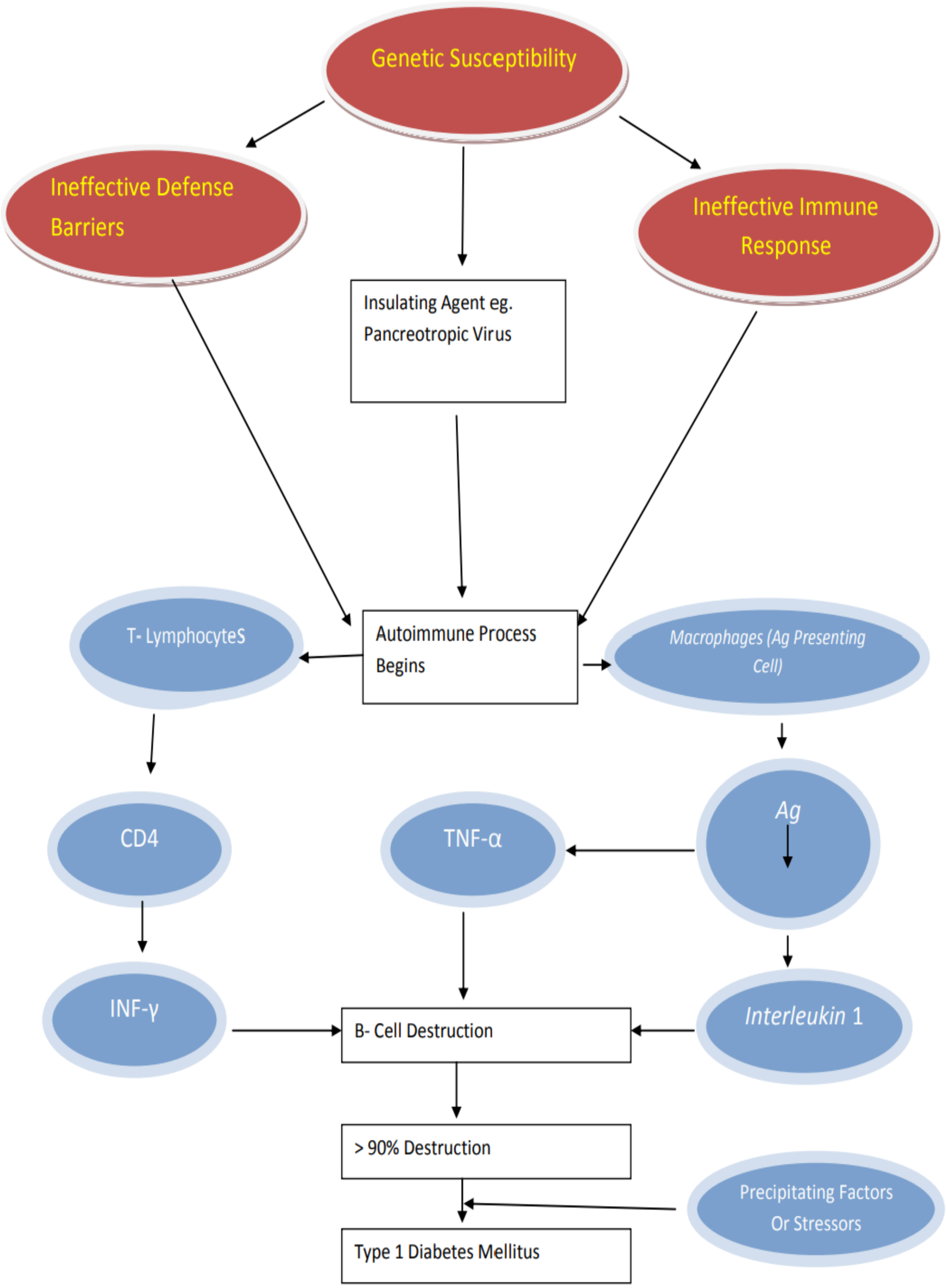


Geographical distribution of type-1 diabetes mellitus.

Pathogenesis of T1DM

Type 1 diabetes mellitus is a chronic autoimmune disease characterized by the selective destruction of insulin-producing pancreatic β-cells (Figure 1). The onset of clinical disease signifies the end stage of β-cell destruction leading to type 1 diabetes mellitus.[20] Several features characterize type 1 diabetes mellitus as an autoimmune disease, as explained by Al Homsi and Lukic (1992). These include the presence of immuno-competent and accessory cells in infiltrated pancreatic islets, association of susceptibility to the disease with the class II (immune response) genes of the major histocompatibility complex (MHC; human leucocyte antigens HLA), and the presence of islet cell-specific autoantibodies. Additionally, alterations in T cell-mediated immunoregulation, particularly within the CD4+ T cell compartment, play a significant role. The involvement of monokines and TH1 cells producing interleukins in the disease process, the response to immunotherapy, and the frequent occurrence of other organ-specific autoimmune disorders further underscore the autoimmune nature of type 1 diabetes mellitus.[21]

Figure.2 Pathogenesis of T1DM[21]



Factors Responsible for Increasing incidence of T1DM

Mode of Delivery & Breastfeeding

The mode of delivery, particularly caesarean section, has been associated with an increased risk of T1DM. Caesarean delivery may alter the neonatal microbiome by limiting exposure to maternal flora, potentially affecting immune system development and increasing T1DM risk. The global rise in caesarean section rates could be contributing to the increasing prevalence of T1DM.[22-24]

Breastfeeding has been found to have a protective effect against T1DM. Children who were never breastfed or were breastfed for shorter periods are at higher risk of developing T1DM. Breastfeeding is believed to reduce the risk of T1DM by positively influencing gut microbiota and the infant's immune system, although the role of early introduction of cow's milk remains unclear.[25,26]

Childhood Obesity and Body Mass Index (BMI)

Recent studies indicate a correlation between higher body mass index (BMI) and an earlier onset of type 1 diabetes mellitus (T1DM), with increased adiposity linked to low-grade inflammation and the release of pro-inflammatory cytokines that promote the autoimmune destruction of β-cells.[27-30] The accelerator hypothesis suggests that insulin resistance from obesity triggers this autoimmune response.[31] Additionally, high cholesterol levels are associated with increased T1DM incidence. Population studies show that hypercholesterolemia may predispose individuals to T1DM through mechanisms like oxidative stress, inflammation, and β-cell apoptosis, with statins helping to preserve β-cell function.[32] Despite some conflicting findings, the majority of research supports a link between increased BMI, high cholesterol levels, and T1DM development.

Dietary Habits

Modern dietary habits, including high meat consumption and diets rich in proteins and fermentable fibres, have been linked to higher T1DM incidence.[33-35] The abundance of readily available food in modern societies is thought to contribute to this trend. This phenomenon has been observed historically, such as the significant increase in T1DM incidence following the reunification of Germany.[36]

Hygiene Hypothesis and Microbial Exposure

The hygiene hypothesis postulates that reduced childhood exposure to microbes leads to an increased risk of autoimmune diseases, including T1DM.[37] There is a significant negative correlation between infectious diseases & incidence and mortality from T1DM, suggesting that microbial exposure during childhood helps the immune system develop properly. Additionally, maternal infections during pregnancy and reduced antibiotic exposure in early life are associated with a lower T1DM risk.[38]

Pollution

Exposure to environmental pollutants, such as ozone, particulate matter, and nitrogen oxides, has been linked to an increased risk of developing T1DM. These pollutants can induce oxidative stress, inflammation, and apoptosis, contributing to β-cell destruction. The rise in environmental pollution due to human activity is a significant concern for T1DM incidence.[39]

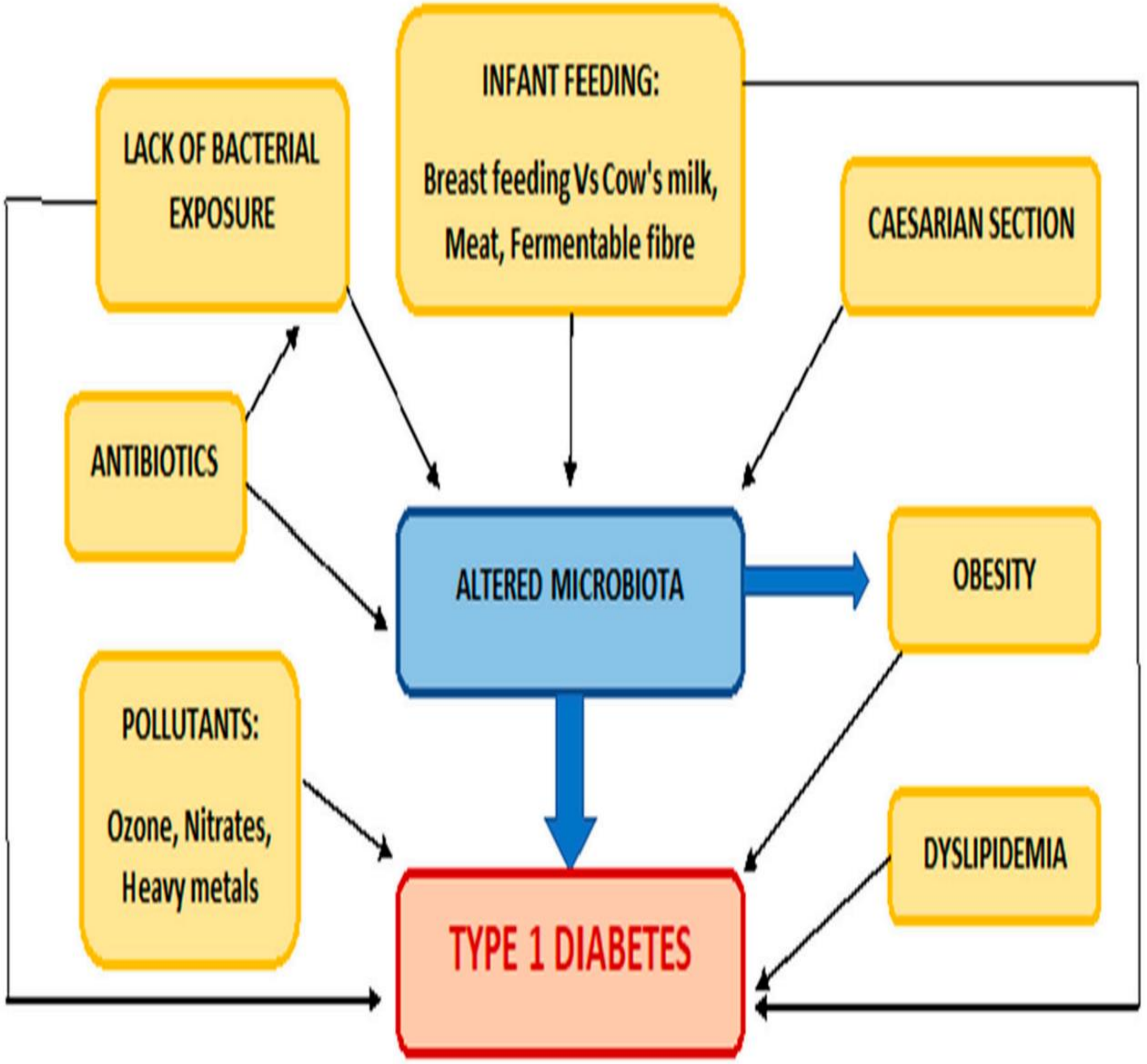
Ecological and Geographical Factors

Geographical factors, including proximity to the sea and latitude, influence T1DM incidence. Higher T1DM prevalence is observed in northern latitudes, possibly due to lower vitamin D levels. Migrant studies have shown that populations moving to high-income countries acquire the T1DM risk profile of their new environment, highlighting the role of environmental factors over genetic predisposition.[40]

Gut Microbiome

The modulation of the gut microbiome appears to be a key mechanism through which environmental factors influence T1DM risk. Factors such as mode of delivery, breastfeeding, diet, and antibiotic use impact the gut microbiota, which in turn affects immune system development and the risk of autoimmune diseases like T1DM. Understanding these interactions is crucial for developing strategies to prevent or delay the onset of T1DM.[41]

Figure.3-Factors Responsible for Increasing incidence of T1DM [42]



Clinical features and complications of T1DM

Signs and symptoms of severe insulin deficiency and hyperglycaemia include: polydipsia (increased thirst), polyphagia (increased appetite), polyuria (increased urination), weight loss, and fatigue. These are due to defective transport of glucose from the bloodstream into tissues, resulting in increased glucose levels in the blood, elevated glucose in the urine, and concomitant calorie and fluid losses in the urine.[42] When insulin levels fall to such low levels that lipolysis cannot be suppressed, products of fat metabolism called ketone bodies (primarily acetoacetate and β- hydroxybutyrate) accumulate in the blood, leading to metabolic acidosis and compensatory respiratory alkalosis due to hyperventilation. If untreated, compensatory mechanisms eventually fail and ketoacidosis results in cerebral oedema, mental confusion, unconsciousness, coma, and death.[43]

Diagnostic criteria:

1. Fasting plasma glucose ≥ 126 mg/dl
2. Post-Prandial glucose ≥ 200 mg/dl
3. HbA1c ≥ 6.5%
4. Random glucose ≥ 200 mg/dl with symptoms

Characteristic of T1 diabetes:

1. Urine/blood ketones: moderate-large (in > 50%)
2. Continuous requirement of insulin since diagnosis.[44]

Advancements in T1DM Management

Following the advent of insulin therapy, the mid-20th century saw significant advancements in the management of T1DM. The development of blood glucose monitoring devices in the 1970s allowed for better control of blood sugar levels, significantly improving the quality of life and prognosis for people with T1DM. The 1980s and 1990s brought further innovations with the introduction of synthetic human insulin, produced through recombinant DNA technology, and insulin analogues, which provided more precise control over blood sugar levels by mimicking the body's natural insulin patterns more closely. Continuous subcutaneous insulin infusion (CSII) or insulin pump therapy also emerged during this period, offering another means of tight glucose control.[45]

Factors influencing Quality of life & Well-being in T1DM Patients

Quality of life for people with Type 1 Diabetes (T1DM) depends on many factors, including medical care, mental health, social support, and lifestyle choices. Keeping blood sugar levels in check is crucial. This means regularly checking blood sugar, taking insulin, eating a balanced diet, and staying active. Access to advanced medical devices like continuous glucose monitors and insulin pumps can make managing diabetes easier and help prevent complications. Learning about diabetes and how to manage it day-to-day is also important for staying healthy and avoiding problems. [46]

Mental and social aspects are also very important. Support from family, friends, and healthcare professionals can reduce the stress and worry that come with having a chronic illness. Mental health services, such as counselling and support groups, can help patients deal with the emotional challenges of T1DM. It's also important for people with T1DM to feel accepted and understood in places like schools and workplaces to avoid stigma and improve social interactions. Financial stability to afford medical supplies and treatments, as well as having good health insurance, can greatly reduce stress and improve overall quality of life. All these factors together help improve life for people with T1DM. [47]

Care Givers Burden

Caring for individuals with Type 1 diabetes mellitus (T1DM) can impose a significant burden on caregivers. The relentless nature of T1DM management, which includes monitoring blood glucose levels, administering insulin, adhering to dietary restrictions, and managing potential complications, demands continuous attention and vigilance. Caregivers often experience emotional strain, worry, and stress associated with the responsibility of ensuring optimal disease management and the well-being of their loved ones or patients. Moreover, the unpredictability of T1DM, with fluctuations in blood sugar levels and the risk of acute and long-term complications, adds to the caregiver's burden. Balancing caregiving responsibilities with other aspects of life, such as work and personal commitments, can further exacerbate the challenges faced by caregivers.[48]

- Kalyva et.al., 2009 conducted a study in Greece to assess the health-related quality of life (HRQoL) in children and adolescents with Type 1 Diabetes Mellitus (T1DM) compared to healthy controls. They included 117 participants with T1DM aged 5–18, along with their parents, and 128 matched healthy children and adolescents. The study used the PedsQL™ 4.0 Generic Core Scales for general HRQoL and the PedsQL™ 3.0 Diabetes Module for diabetes-specific HRQoL assessments. Findings revealed that children and adolescents with T1DM reported lower overall HRQoL compared to their healthy counterparts. Parents perceived a more significant impact of the illness on their children's lives than the children themselves did. Factors associated with better HRQoL included later onset of diabetes, fewer hyperglycemic episodes, lower HbA1c levels, older age, and male gender.[49]

- Anke Nieuwesteeg et.al., 2012 conducted a systematic review covering studies from 2000 to May 2012 to examine the impact of Type 1 Diabetes Mellitus (T1DM) on the quality of life (QoL) of children and adolescents. Out of 17 eligible studies reviewed, effect sizes were calculated to assess how T1DM affects QoL. The findings indicated that, overall, children and adolescents with T1DM do not experience a significant impairment in their general QoL compared to their healthy peers. However, they do face specific QoL challenges related to diabetes, such as difficulties in daily activities and concerns about the condition itself. The review highlighted the need for longitudinal research to better understand these challenges and to develop personalized care strategies for children with T1DM of all ages.[50]

- F. Sundberg et.al., 2014 conducted a study focusing on children under 7 years old with Type 1 diabetes mellitus (T1DM) compared to healthy children of the same age. The study aimed to assess health-related quality of life (HRQoL) and its correlation with insulin treatment and glycemic control. The participants included 24 children with T1DM (12 girls, average age 4.5 years) and 27 healthy children (14 girls, average age 4.6 years). Both groups completed the Pediatric Quality of Life Inventory 4.0 Generic Core Scales, while children with diabetes also completed the Pediatric Quality of Life Inventory 3.0 Type 1 Diabetes Module Scales. HbA1c levels were measured for children with T1DM, and glucose meter memories were analyzed. Results showed that parents of children with T1DM rated their children's generic HRQoL lower than parents of healthy children (score: 80 vs 91; P = 0.003). This difference was more pronounced in children under 5 years old (score: 79 vs 93; P = 0.004). Additionally, 22% of parents of children with T1DM considered their child's HRQoL to be a concern compared to the general population. Among children aged 5 to 7 years with T1DM, 40% rated their own HRQoL similarly. These findings underscored challenges in HRQoL for young children with T1DM, emphasizing the need for targeted interventions to improve their well-being.[51]

- Mi-Kyoung Cho et.al., 2016 conducted a cross-sectional descriptive study to explore factors influencing the quality of life (QOL) of individuals with Type 1 Diabetes Mellitus (T1DM). The study involved 111 participants with T1DM, and data analysis was performed using the PASW Statistics program. Hierarchical multiple regression was employed to identify significant predictors of QOL.The findings indicated that four main variables significantly influenced QOL: blood glucose levels during hypoglycemia and complications (Model 1), and efficacy for self-management of diabetes and acceptance of the disease (Model 2).

Together, these variables explained a substantial portion of the variance in QOL among participants. The study underscored the critical importance of managing severe hypoglycemia, preventing complications, and enhancing coping mechanisms for effective diabetes self-management. It recommended developing targeted interventions aimed at improving these aspects to enhance QOL among individuals living with T1DM.[46]

- Marta Murillo et.al., 2017 conducted a descriptive study involving 136 patients diagnosed with Type 1 Diabetes Mellitus (T1DM) across five hospitals in Spain. The study included patients who had been diagnosed for more than six months, were over eight years old, and did not have cognitive impairments. Health-related quality of life (HRQoL) was evaluated using the EuroQOL-5D and KIDSCREEN instruments, while mental health status was assessed using the Strengths and Difficulties Questionnaire.

  The findings indicated that physical well-being scores were lower, particularly among girls. Older children (age over 11 years) and those from single-parent households exhibited lower adherence to treatment regimens. Additionally, lower satisfaction in the Quality-of-life dimension was associated with being overweight. These results highlight the multifaceted impact of T1DM on HRQoL, emphasizing the need for tailored approaches to improve treatment adherence and overall well-being in pediatric patients with diabetes.[52]

- Benjamin D. Capistrant et.al., 2017 conducted a study in Nagpur, Maharashtra, focusing on caregivers of children with Type 1 Diabetes Mellitus (T1DM) recruited from the Diabetes Research Education and Management (DREAM) Trust. The study utilized the Zarit Burden Scale and PHQ-9 to assess the impact of caregiving burden on caregivers' depression and well-being. The findings indicated that among Indian caregivers of children with T1DM, experiencing high subjective burden and direct caregiving burden were linked to an increased risk of caregiver depression and poorer overall well-being. This highlights the significant psychological and emotional toll that caregiving for children with T1DM can have on caregivers in India, underscoring the need for support interventions to alleviate burden and improve caregivers' mental health.[9]

- A. J. N. Raymakers et.al., 2018 conducted a study using baseline data from a cluster-randomized trial involving patients with Type 1 diabetes from six centers across Ireland. Health-related quality of life (HRQoL) was assessed using the three-level EuroQol EQ-5D measure, focusing on individual dimensions of the EQ-5D to understand patient-reported outcomes. A total of 437 Type 1 diabetes patients participated, with a median age of 40 years (IQR: 31-49), and 53.8% were female. Overall, patients reported a high HRQoL based on EQ-5D scores, with 54% reported perfect HRQoL. Among those reported issues, the most common concern was related to the anxiety/depression dimension (29.6%). In multivariate regression analysis, self-reported mental illness (-0.22 (95% CI: -0.34, -0.10)) and unemployment status (-0.07 (95% CI: -0.13, -0.02)) were found to negatively impact EQ-5D scores ($p < 0.05$). Sensitivity analyses confirmed the persistent influence of self-reported mental illness on HRQoL. The study highlights significant proportions of Type 1 diabetes patients experiencing challenges related to mental health dimensions, suggesting opportunities to enhance HRQoL through targeted interventions addressing these issues.[53]

- Nisha Bhavani et.al., 2018 conducted a study within the pediatric endocrinology division of a tertiary referral private university teaching hospital in Kerala. The study included patients with Type 1 Diabetes Mellitus (T1DM) diagnosed before the age of 21 and with at least one year of disease duration, who had visited the hospital within the previous six months. A total of 107 patients participated, completing a newly translated and validated regional language (Malayalam) version of the Pediatric Quality of Life Inventory (PedsQL) 3.2 Diabetes Module to assess their HRQoL. The study found that 14.9% of patients had microvascular complications. Overall, patients with T1DM reported lower general HRQoL compared to their peers without diabetes. Parents of these patients indicated lower scores in diabetes management and expressed greater concern about the disease, particularly among those with a younger age of onset of diabetes. These findings underscore the impact of T1DM on both patients and their caregivers, highlighting the need for targeted support and interventions to improve overall well-being and disease management.[10]

- Catherine Kyokunzire et.al., 2018 conducted a facility-based cross-sectional study involving 200 children and adolescents with Type 1 diabetes at two major diabetes clinics in Kampala. Caretakers of these patients were interviewed using pretested questionnaires to gather data on sociodemographic characteristics, diabetes care practices, knowledge, attitudes, and adherence to diabetes management recommendations. The study found that overall adherence to diabetes care recommendations among the participants was 37%. However, adherence rates varied significantly for different aspects of treatment: 52% for insulin therapy, 76.5% for blood glucose monitoring, and 29.5% for dietary recommendations. These findings indicate that adherence to diabetes care, particularly dietary guidelines, remains notably low in this population. The study highlights the importance of reinforcing caretaker involvement to enhance adherence to diabetes management recommendations among children and adolescents with Type 1 diabetes in Kampala. Strategies focusing on educating and supporting caretakers could potentially improve overall treatment adherence and health outcomes in this vulnerable group.[54]
- Nicholas Bari Ndahura et.al., 2019 conducted a cross-sectional study across six diabetes clinics in Uganda involving 59 caregivers and 61 children with Type 1 Diabetes Mellitus (T1DM). The study utilized the T1DM Nutrition Knowledge Survey (N.K.S.) to evaluate caregivers' understanding of nutrition related to T1DM, and collected dietary intake data from children using 24-hour dietary recall and Dietary Diversity Score (D.D.S.) questionnaires. The findings indicated that a significant majority of caregivers had inadequate T1DM nutrition knowledge. The study also observed that children with T1DM often consumed excessive carbohydrates while having inadequate intake of proteins, fats, and essential micronutrients. Caregivers with lower levels of education tended to demonstrate poorer nutrition knowledge regarding T1DM. This study underscores the critical need for targeted nutritional education programs aimed at caregivers of children with T1DM in Uganda. Improving caregivers' knowledge about appropriate dietary management for T1DM could potentially enhance the nutritional intake and overall health outcomes of children living with this condition.[55]

- Rosana de Morais Borges Marques et.al., 2020 conducted a cross-sectional study focusing on adolescents of both sexes, aged between 10 and 18 years, who had Type 1 Diabetes Mellitus (T1DM). Quality of life (QOL) was assessed using a specific instrument designed for young diabetics, alongside anthropometric measurements. Among the 53 adolescents with T1DM included in the study, more than 13% rated their QOL as poor. The study identified that being overweight, as indicated by Body Mass Index (BMI), was associated with lower satisfaction in the QOL satisfaction dimension. Additionally, females showed a significant association with poorer QOL in the impact dimension. The findings underscore the importance of addressing QOL issues and related factors among adolescents with T1DM. The study suggests the need for health interventions and strategies aimed at comprehensively improving the well-being of these patients, emphasizing the management of weight and gender-specific considerations to enhance overall QOL outcomes.[56]

- Niraj Kumar et.al., 2020 conducted a cross-sectional study at a tertiary care hospital in northern India involving 146 children with Type 1 Diabetes Mellitus (T1DM). After applying inclusion and exclusion criteria and obtaining consent, 46 children were enrolled in the study. Quality of life was assessed using the DAWN Youth questionnaire, the WHO-5 Well-being Index, and the Diabetes Treatment Satisfaction Questionnaire (D.T.S.Q.) The study revealed that 83% of the participants belonged to the upper-middle-income group, with 17% classified as obese and 8% as anemic. The WHO-5 Well-being Index indicated poor well-being in 17% of patients, while 26% reported experiencing low mood. Hyperglycemia was perceived by 48% of participants, and 30.4% reported episodes of hypoglycemia. Factors such as recent diagnosis, older age at onset of diabetes, and elevated HbA1c levels were associated with a higher prevalence of psychological and cognitive problems among the children studied. These findings highlight the diverse challenges faced by children with T1DM in northern India and underscore the importance of addressing both physical and psychological aspects of their health through targeted interventions and support strategies.[57]

- Dilara Keklik et.al., 2020 conducted a descriptive study to assess the care burden and quality of life among mothers of children with Type 1 Diabetes Mellitus (T1DM), as well as to explore the correlation between these two variables. The study included 106 mothers of children with T1DM. Data collection utilized a descriptive questionnaire, the Zarit Caregiver Burden Interview, and the WHOQOL-BREF quality of life scale. Statistical analysis involved methods such as the Mann-Whitney U test, Student's t-test, ANOVA, Kruskal-Wallis test, and Spearman's correlations. The findings indicated that mothers experienced a moderate level of caregiving burden, with a mean score of 34.95 ± 12.48. Income level was found to significantly influence the caregiving burden, with higher burden associated with lower income states ($p < 0.05$). Quality of life dimensions such as physical well-being were significantly affected by the time of diagnosis, while environment-related quality of life was influenced by income level ($p < 0.05$).Overall, the study highlighted a negative correlation between caregiving burden and several aspects of quality of life among mothers of children with T1DM. These results underscore the significant impact of caregiving responsibilities on maternal well-being and emphasize the need for supportive interventions tailored to alleviate burden and enhance quality of life in this population.[58]
- Huijuan Tong et.al., 2021, Conducted a semi-structured interviews lasting 45–60 minutes were conducted with 20 parental caregivers of children diagnosed with Type 1 Diabetes Mellitus (T1DM) at the Pediatric Neuroendocrinology Department of Shengjing Hospital, China Medical University in Shenyang. The caregivers, aged 30–53 years and comprising 7 fathers and 13 mothers, discussed various challenges they face. Content analysis identified five main themes with thirteen subthemes: persistent psychological stress, including catastrophic emotions and emotional distress; changes in family dynamics such as altered life patterns and shifting parental roles; difficulties in daily diabetes management involving technical challenges and emotional regulation; financial strain due to treatment costs; and insufficient social support and limitations in support systems..[59]
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- Patricia Davidson et.al., 2022 conducted a systematic review of English language studies published between January 1, 2007, and March 31, 2020, using a modified Cochrane review methodology. They included randomized controlled trials (RCTs) that involved participants with Type 1 Diabetes Mellitus (T1DM), with or without caregivers, and evaluated the impact of diabetes self-management education (DSME) interventions or components of the ADCES7™ Self-Care Behaviors on Quality of Life (QoL) as either a primary or secondary outcome. Through a rigorous three-tiered review process, they identified 19 articles reported on 17 RCTs that met their inclusion criteria. Among these, seven studies highlighted significant improvements in QoL outcomes attributed to DSME interventions, though outcomes varied across participant demographics, QoL assessment tools (generic vs. diabetes-specific), intervention types, durations, and the roles of interventionists. These findings underscore the diverse impacts of DSME on QoL outcomes, emphasizing the need for tailored interventions to enhance well-being among individuals with T1DM and their caregivers.[60]

- Bisrat Tamene Bekele et.al.,2022 conducted a hospital-based cross-sectional study involving 379 randomly selected children and adolescents aged 5–18 years with Type 1 Diabetes Mellitus (T1DM), who were attending endocrine clinics in Ethiopia between August 25 and September 25, 2021. They used the PedsQL™ 4.0 Generic Core Scales to assess Health-Related Quality of Life (HRQoL). The study employed both bivariable and multivariable linear regression analyses to identify significant predictors of HRQoL. The findings indicated that children and adolescents with T1DM in Ethiopia generally have favorable HRQoL. Factors such as older age, longer duration of diabetes, and frequent insulin administration (three times per day) were associated with lower HRQoL scores. Conversely, having educated parents, an employed father, and regular blood glucose monitoring were linked to higher HRQoL scores.[1]

- Heike Sabmann et.al., 2022 Conducted a study in 9 german paediatric diabetes centers. Aim is to investigate (1) daily, emotional, and physical caregiving burdens in parents of children with type 1 diabetes, (2) the sociodemographic and clinical predictors of three burdens, and (3) support measures that parents wish to receive. Data from 1,107 parents (83% mothers) were analyzed. Parents reported significantly higher emotional burdens compared to daily and physical burdens ($p < 0:0001$). Mothers felt more burdened than fathers did. Parents of younger children reported higher daily and physical burdens compared to the parents of older children, and similarly, parents of technology users reported higher daily and physical burdens compared to the parents of nontechnology users. However, emotional burdens did not differ in both comparisons[48].

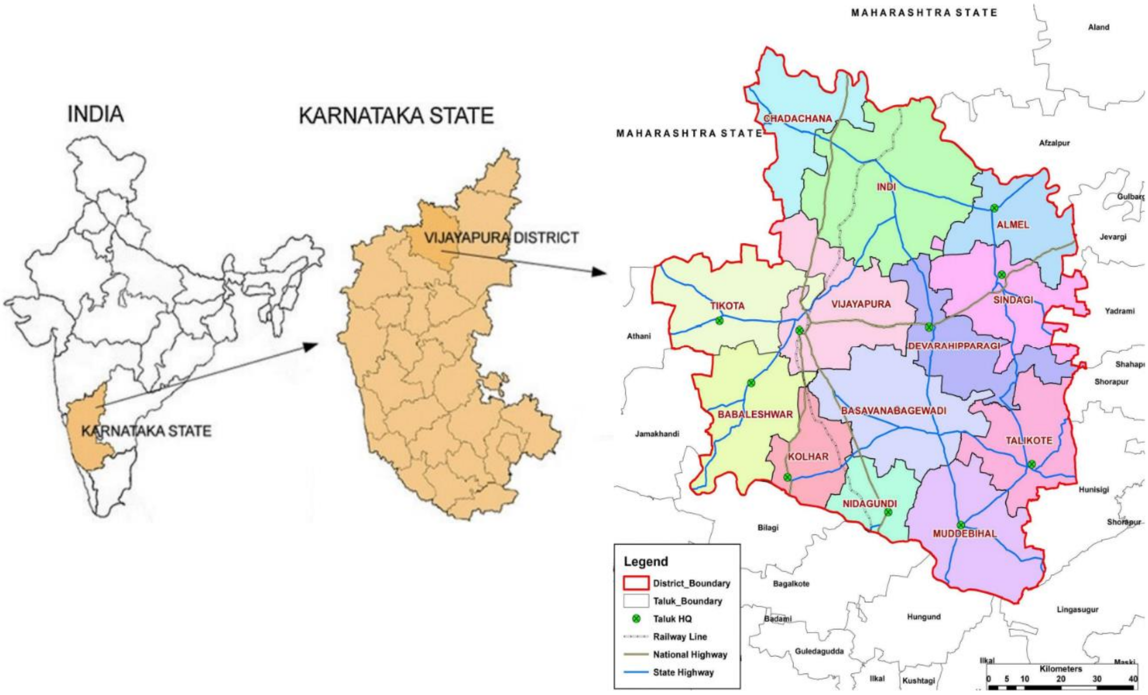
- Ewa Kobos et.al., 2023 conducted a study involving 125 caregivers of children with type 1 diabetes to examine caregiver burden and feelings of loneliness. They used the Caregiver Burden Scale and the Revised UCLA Loneliness Scale to gather data. The study found that caregivers experienced an average level of burden, with the highest burden reported in the General Strain Subscale. Mothers generally experienced greater caregiving burden than fathers, particularly in the General Strain Subscale, and caregivers of younger children felt more burdened in the Isolation and Disappointment Subscales. A moderate to high level of loneliness was reported by 4.8% of caregivers. The study concluded that increased caregiver burden in those caring for children with type 1 diabetes is associated with greater feelings of loneliness.[61]

- Lourdes Balca´zar-Herna´ndez et.al.,2023 conducted a study focusing on Primary Informal Caregivers (PIC) of children and adolescents with type 1 diabetes mellitus (T1DM). They used the Zarit Burden Interview Scale (ZBIS) to assess caregiver burden, the Beck Depression Inventory (BDI-II) to evaluate depression among PIC, and the Family APGAR questionnaire to gauge family functionality. The study included 100 PIC, among whom 33% experienced caregiver burden. The Zarit scale indicated a total score of 41 (with a range of 34–49); 19% had mild caregiver burden, and 14% had severe caregiver burden. According to the BDI-II, 82% had minimal depression, 11% had mild depression, 5% had moderate depression, and 2% had severe depression. Family function was assessed as good in 69% of cases, with 13% experiencing moderate dysfunction and 18% severe dysfunction. The study found a significant positive correlation between caregiver burden and BDI-II scores ($r = 0.84$; $p = 0.001$), as well as the severity of depression ($r = 0.87$; $p = 0.001$). A logistic regression analysis indicated that higher BDI-II scores were associated with increased caregiver burden (OR 1.14; 95% CI 1.061–1.23; $p = 0.001$).[62]

MATERIALS AND METHODS

Background Details: This Study was done in Vijayapura district, North Karnataka. District has 5 talukas, namely Bijapur, Basavana bagewadi, Indi, Muddebihal & Sindagi. Major occupation is agriculture, with a population of 21,77,331. It's a developing district, 70% of the population live in rural areas. Children and early youth constitute 28% of the Overall population.

Figure.4-Map of Vijayapura district



Study Population:

This study was conducted among T1DM patients in the age group 6 to 25 years and their Primary caregivers.

Study Period: March 2023 to April 2024 (1 year)

Study Design: Cross-Sectional Study

Ethical consent and assent:

1. Assent was obtained from T1DM patients under 18 years old, along with consent from their caregivers for participation in the study.

2. Consent was obtained from T1DM patients over 18 years old and their primary caregivers for participation in the study.

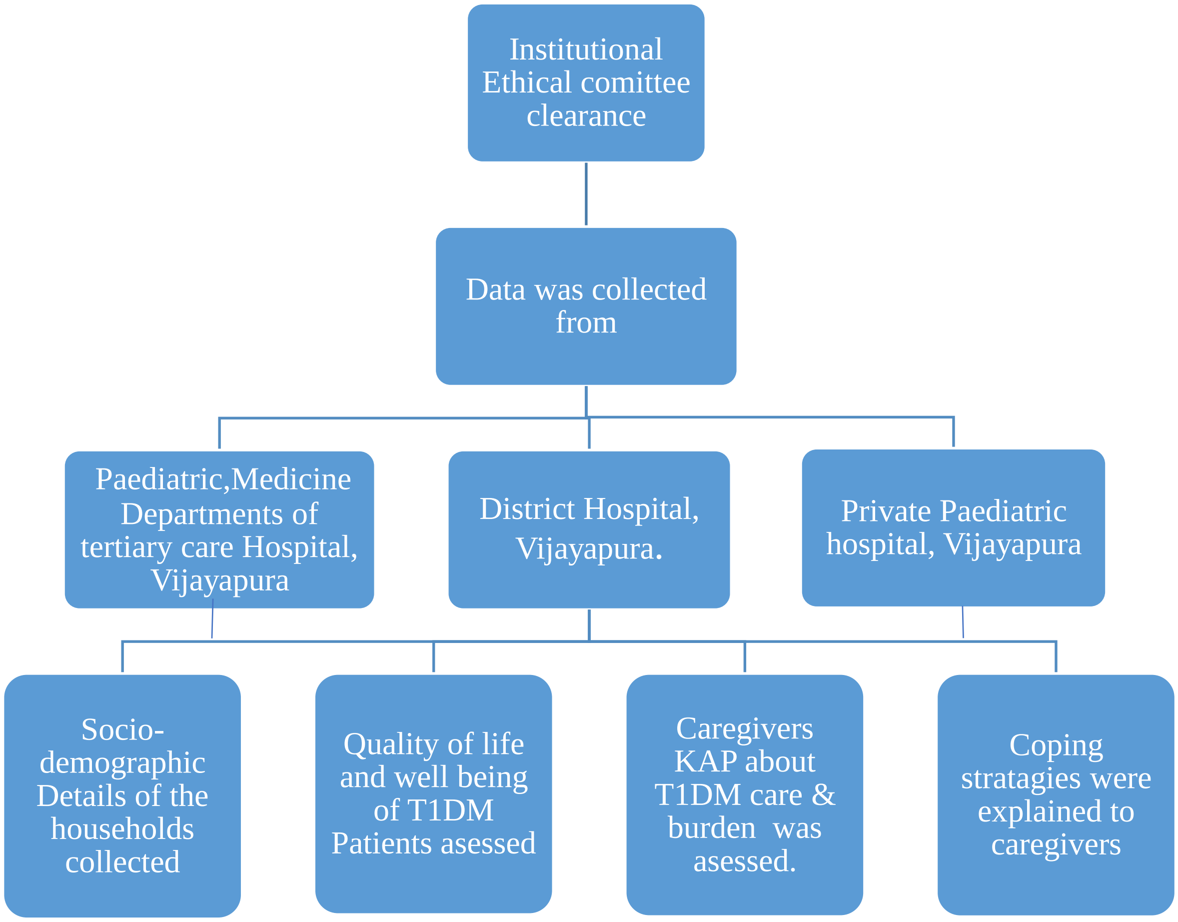
Study Technique:

This Study was conducted through in person interviews with T1DM Patients and their Caregivers after acquiring their consent to participate. A pre-tested semi-structured questionnaire was used for assessment of sociodemographic factors of T1DM Patients, KAP of caregivers towards Type1 DM management.

Standard & Validated Scales in Indian context were used to assess Quality-of-life (QOL) using the Dawn youth questionnaire, WHO-5 well-being index was used for the screening of wellbeing and caregiver burden was evaluated using standard Zarit burden Interview.

All questionaries were created in English and translated into the local language (Kannada) and administered after pilot testing. Pilot testing was done on 10 samples, Necessary changes were made, before the proper data collection. Principles of ethics& confidentiality was maintained and observed.

Study Plan:



Operational definition of T1DM Patient: It is also known as juvenile diabetes and it is a lifelong condition, in which the pancreas produces little to no insulin.

Two main characteristic findings of T1DM Patients are

1.Urine/blood ketones: moderate-large (in > 50%)

2.Continuous requirement of insulin since diagnosis

Primary Caregiver of T1DM Patient: Parent or any relative who provides consistent, daily support to a person with Type 1 Diabetes Mellitus, ensuring the effective management of the condition. This support includes, Blood Glucose Monitoring, Insulin Administration, Diet and Nutrition Management, Emotional Support.

Inclusion Criteria:

- T1DM Patients between the age group of 6 to 25 years
- Patients Those who were diagnosed at least three months prior to the study was included.

Exclusion Criteria:

- Patients less than six years of age
- Patients suffering from a any known mental illness & retardation
- Those who are seriously ill and admitted in ICU due to complications were excluded.

Sample size: With anticipated Mean±SD of Quality of life 32.5±13.8,[57] the study required a sample size of 112 patients, with a 95% level of confidence and a precision of 2.6.[63]

Formula used was

n=z 2 S 2

d 2

Where Z= Z statistic at α level of significance

d 2 = Absolute error

S—Common standard deviation

Sampling Technique & Data collection method: Information about T1DM was collected from the OPD'S& IPD'S of Tertiary care medical college hospital, District hospital & Private pediatric hospital which cater for T1DM Cases from all over the Vijayapura district.

The T1DM Patients who fulfilled the inclusion criteria, attending OPD/IPD'S of the 3 selected Hospitals were included in our study.

1. **District Hospital**: Patients attending OPD/IPD of pediatric and medicine departments were included, List from the district surveillance unit was acquired to contact the remaining T1DM patients, such patients were interviwed at their households.
2. **Tertiary care medical college & Hospital:** Data collected from the T1DM Patients, who were attending OPD/IPD's of both pediatric and medicine departments.
3. **Private Pediatric tertiary care Hospital:** It was selected since caters for majority of T1DM cases, also maintains T1DM Registry and provides free insulin.

The study protocol received approval from the Institutional Ethical Committee of Shri B M Patil Medical College. Permissions to conduct the research were secured from the heads of the Medicine and Pediatric Departments at a tertiary care hospital, a district hospital, as well as private pediatric hospital. Before data collection commenced, the purpose of the study was thoroughly explained to the participants. Each participant received an information sheet in their native language to ensure clear understanding. Written informed consent was obtained from both the patients and their caregivers, emphasizing the voluntary nature of their participation.

To maintain privacy and confidentiality, interviews were conducted in areas separate from the main clinical settings. This approach aimed to create a comfortable environment for the participants, encouraging open and honest responses.

Interview technique was used to elicit data on sociodemographic, Quality of life & Wellbeing of T1DM patients and caregiver burden:

1. For patients younger than 12 years old or those who were unable to respond independently, we collected data through joint interviews with both the patient and their mother. This approach ensured comprehensive and accurate information.

2. Patients aged 12 years and older provided responses directly, allowing us to gather data from their personal perspectives and experiences.

In some instances, specifically for 7 to 8 cases, home visits were conducted to gather data. Following the completion of data collection, coping strategies were explained to caregivers regarding the T1DM care. Patients who were identified as having significant issues were referred for further evaluation and appropriate management. This ensured that the study not only gathered valuable data but also contributed to the immediate well-being of the participants.

Investigations / Interventions:

HbA1c: Also known as glycolate haemoglobin test or A1C test, is used to measure the blood sugar levels in the body. This blood test value indicates the average blood sugar level for the past 2-3 months.

We used a standard, validated, FDA-approved HBA1C onsite kit from PTS Diagnostics. The patient was informed about the procedure and assured they could deny the test if any discomfort occurred. Before the finger prick, proper sanitation was carried out. After pricking, waited for two minutes for the results, which were then recorded. The test strips were discarded following biomedical waste management protocols. No harm was caused during the process, and this test was done after patient acceptance.

Study Tools: A semi-structured, pre-tested questionnaire was developed (Annexure I). This questionnaire covered Household socio-demographic aspects including Name, age, address, occupation, educational status, religious affiliation, caste, average monthly income, family type, and size. Other sections included questions to assess the clinical characteristics and treatment characteristics of Type 1 DM Patients. In this study, the Dawn Youth Quality of Life Scale, WHO Well-Being Index, KAP questions for caregivers regarding T1DM care & Zarit caregivers burden Interview were used to assess various aspects of Quality of life, wellbeing of patients and their caregivers' burden.

To assess the participants' socio-economic status, the Modified BG Prasad Classification socio-economic status scale (January 2022)[64] was used, as shown in Table 1.

Table 1- Modified BG Prasad's classification[64]

Social class	Original classification of 1961 per capita income (Rs/month)	Revised classification for January 2022 (Rs/month)
I (Upper class)	100 and above	8220 and above
II (Upper middle class)	50-99	4110-8219
III (Middle class)	30-49	2465 – 4109
IV (Lower middle class)	15-29	1230-2464
V (Lower class)	<15	<1230

Pilot Testing of Study Tool:

To ensure the appropriateness and clarity of these tools, each scale was translated into the local language. These translated versions were then pilot tested with 10 adolescent students. Based on the feedback and results from the pilot testing, necessary corrections and adjustments were made before starting the data collection phase.

Study Variables:

Age: Age was recorded in completed years as told by the participants.

Type of family:

- Nuclear family: It consists of a married couple and their children while they are still regarded as dependents.
- Joint family: It consists of number of married couple and their children live together in the same household. All men are related by blood and women of household are their wives, unmarried sisters and their family kinsmen.
- Three Generation family: It is a family where representatives of three generation are living together. Young married couple continue to stay with their parents and have their own children as well.

Education:

- Never attended school/ illiterate: Not able to read, write and understand in any language.
- Primary school: Studied up to 7th standard.
- High school: Studied up to 8th standard to SSLC.
- PUC/Diploma: Studied up to PUC or any diploma.
- Graduate and above: Studied up to graduation and above.

Occupation:

- Unemployed: Those who are not employed
- Salaried Employees: Those who have a permanent salary every month.
- Agri Labor: Those who work on other’s agricultural land.
- Non-Agri labor: e.g.; coolies, domestic servants etc.
- Small Business: Independent work; e.g.; Businessman, Shop owners etc.
- Cultivation: Those who cultivate crops in their own land.

Interpretation of scales:

Dawn youth QOL Scale: Quality of life questionnaire (published by the DAWN youth project) This is a 22-item validated questionnaire to assess possible problems in the following six domains: Impact of symptoms related to diabetes, impact of the treatment, impact on activities, parents' issues, worry about the future, and perception of one's own health [6]. This was administered to subjects aged 6-25 years (n = 114). Each question has five possible responses, ranging from '0' (never) to '4' (all the time), and the responses are added up to get the total score for the subscale. Higher scores indicate greater adverse impact on QoL. For this study, we considered the adverse impact on QoL in a domain to be significant, if the score for that domain was in the upper half of the possible range.

WHO-5 well-being Index: WHO-5 well-being Index was administered to subjects aged 6-25years (n = 114). It comprises of five positively worded items; related to positive mood, vitality, and general interests; which are rated on a 6- point Likert scale from '0' (not present) to '5' (constantly present). Higher scores indicate better well-being. The raw score was calculated by totaling the figures of the five answers. The raw score ranges from 0 to 25, 0 representing worst possible and 25 representing best possible quality of life. Below 13 indicates poor wellbeing.

Zarit Burden Interview: The Zarit Caregiver Burden Interview (ZBI) was created by Zarit et.al., in 1980 [21]. It is a self-administered instrument composed of 22 items scored on a Likert-type scale with 5 response options: never (0 points), rarely (1 point), sometimes (2 points), quite often (3 points), and almost always (4 points). Scores were Categorized into 0-20 (no Burden), 21-40(mild burden), 41-60 (Moderate burden), 61-80(severe burden). The Kannada translation of the ZBI was used for this study. The ZBI assesses the impact of psychological well-being, financial situation, relationship of the caregiver and person with disability, and social life. Proposals have generated different versions of the scale, which have varied in number of items and factor structure. Sufficient evidence of validity and reliability has been reported in different countries and languages.

Statistical Analysis:

The data was collected using proforma and entered into a Microsoft Excel spreadsheet. We cleaned the data carefully and checked for any missing information. SPSS Version 26 was used to analyze the data. Categorical data were summarized with frequencies and percentages and visually represented through diagrams and figures.

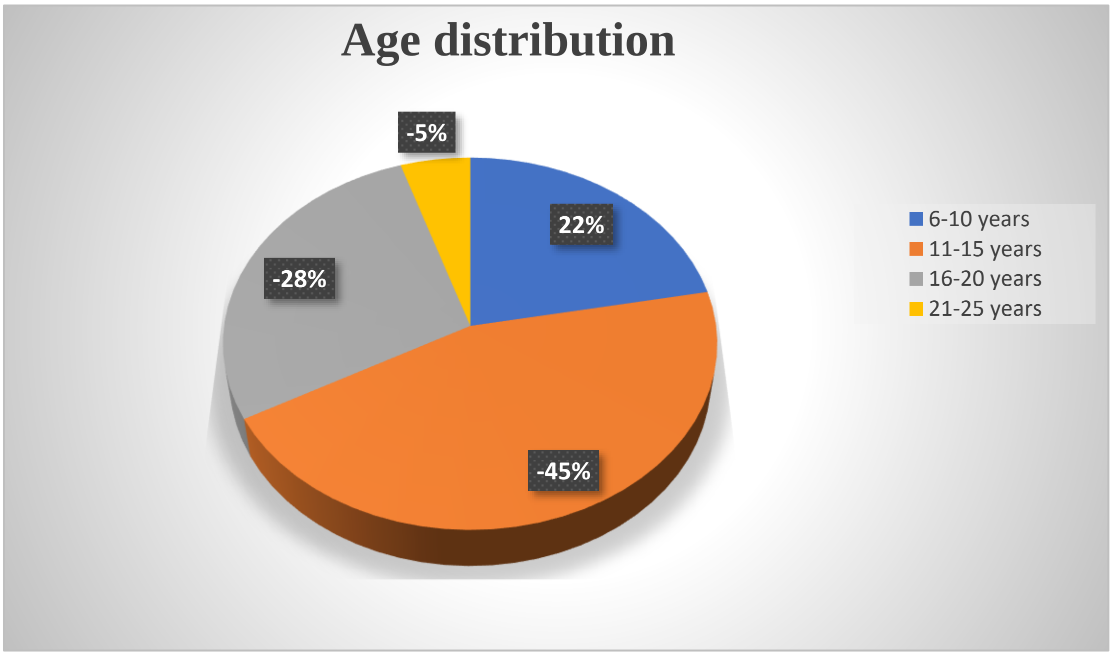
The quality-of-life scores were categorized in all domains as poor quality (50& above) & better quality (below 50). Caregivers Burden Scores were Categorized into 0-20 (no Burden), 21-40(mild burden), 41-60 (Moderate burden), 61-80(severe burden) & Wellbeing scores were categorized as Normal (13& more), Poor wellbeing (below 13).

The Chi-square test was used to explore associations between categorical variables. A P-value of less than 0.05 was considered statistically significant, and all tests were conducted using a two-tailed approach. Binary logistic regression was performed for the variables, which were showing statistically significant association. Odds ratio and Confidence intervals were calculated to estimate the risk.

RESULTS

In our study We Interviewed 114 T1DM Patients and their caregivers from the 3 major Tertiary care hospitals (OPD/IPD's) of the Vijayapura district to explore the quality of life & well-being of the patient and their caregiver's burden. Majority of the caregivers were mothers.

Figure.5 Age Distribution of T1DM Patients (n=114)



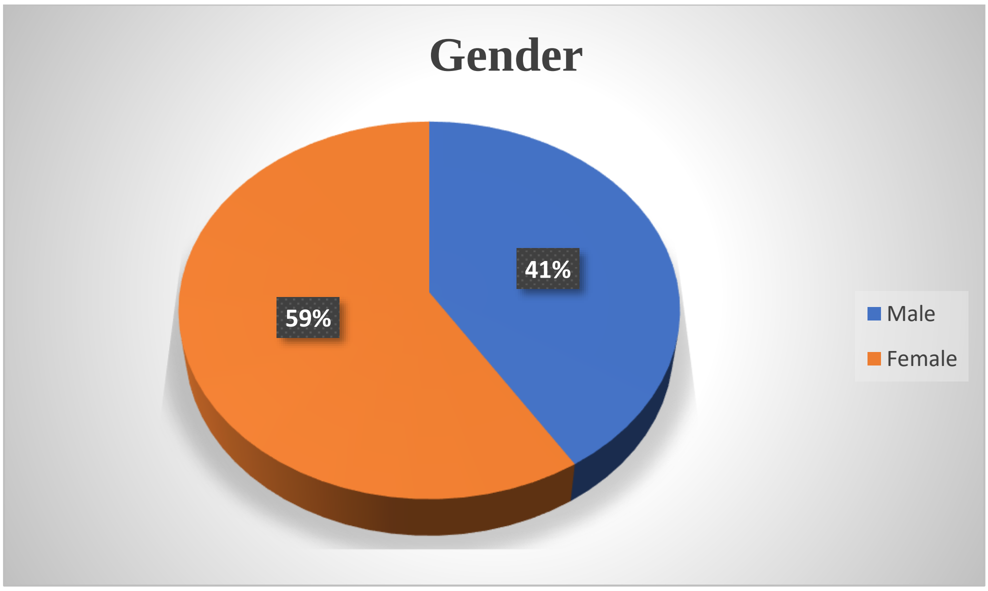
- We observed, out of the 114 participants, the majority of the participants (45%) were in the 11-15 years age group. The 21-25 years age group comprised 5% of the participants, while 28% were in the 16-20 years age group & 22% were in the age group of 6-10 years.

Table.2 Socio-demographic Characteristics of T1DM Patients (n=114)

Characteristics		Frequency	Percentage
Age group (in years)	6-10	25	22
	11-15	51	45
	16-20	32	28
	21-25	6	5
Gender	Male	47	41
	Female	67	59
Residence	Rural	70	61
	Urban	44	39
Education status of Child/Adolescent	Never attended	5	4
	Pre/primary	34	30
	High school	46	41
	PUC/Diploma	18	16
	Degree and above	11	9
Religion	Hindu	104	91
	Muslim	10	9
Caste	General	41	36
	OBC	47	41
	SC	17	15
	ST	9	8
Mothers’ education	Up to Primary school	83	73
	More than primary school	31	27
Fathers’ occupation	Agri labour	39	34
	Small business	28	25
	Salaried Employee	17	15
	Non-Agri labour	25	22
	Expired	5	4
Type of family	Nuclear	95	84
	Three Generation	15	13
	Joint	4	3
Socio economic status	Class 1	6	5
	Class 2	14	12
	Class 3	37	33
	Class 4	39	34
	Class 5	18	16
Primary Care Giver	Mother	86	75
	Other relatives	28	25

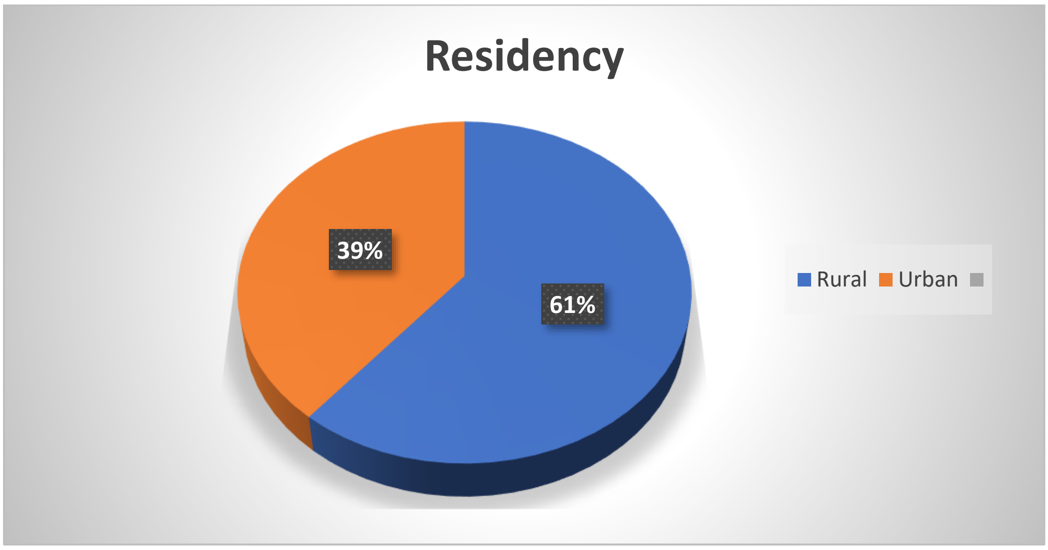
- Table.2-shows the socio-demographic details of T1DM patients, including their caregivers, economic status, family type, caste, religion, education level.
- Most caregivers are mothers (75%), the majority of families are nuclear (84%), and a significant proportion of patients are rural residents (61%). Additionally, most patients fall in the 11-15 years age group (45%), and a large number belong to the OBC caste category (41%).

Figure.6 Gender Distribution of T1DM Patients (n=114)



- Figure.6- It shows among 114 participants, we observed Majority were females with 59% and males were 41%.

Figure.7 Residency of T1DM Patients (n=114)



- Figure.7-Its shows that a majority of the participants, 61%, reside in rural areas, while the remaining 39% reside in urban areas.

Figure.8 Socio economic status of the of T1DM Patients (n=114)

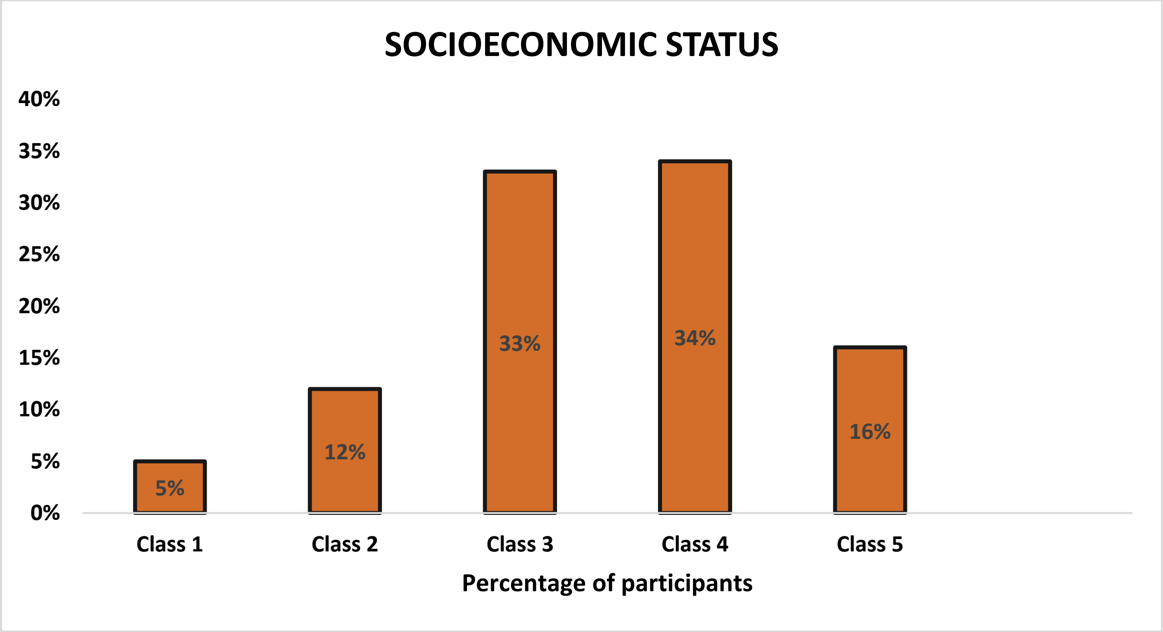


Figure.8-Majority of adolescents belong to the socio-economic class 4-Lower middle class (34%), followed by Class 3 –Middle class (33%) and Class5 – Lower class (16%). Only 5% Were belongs to Class1-Upper class.

Figure.9 Clinical Characteristics of T1DM Patients(n=114)

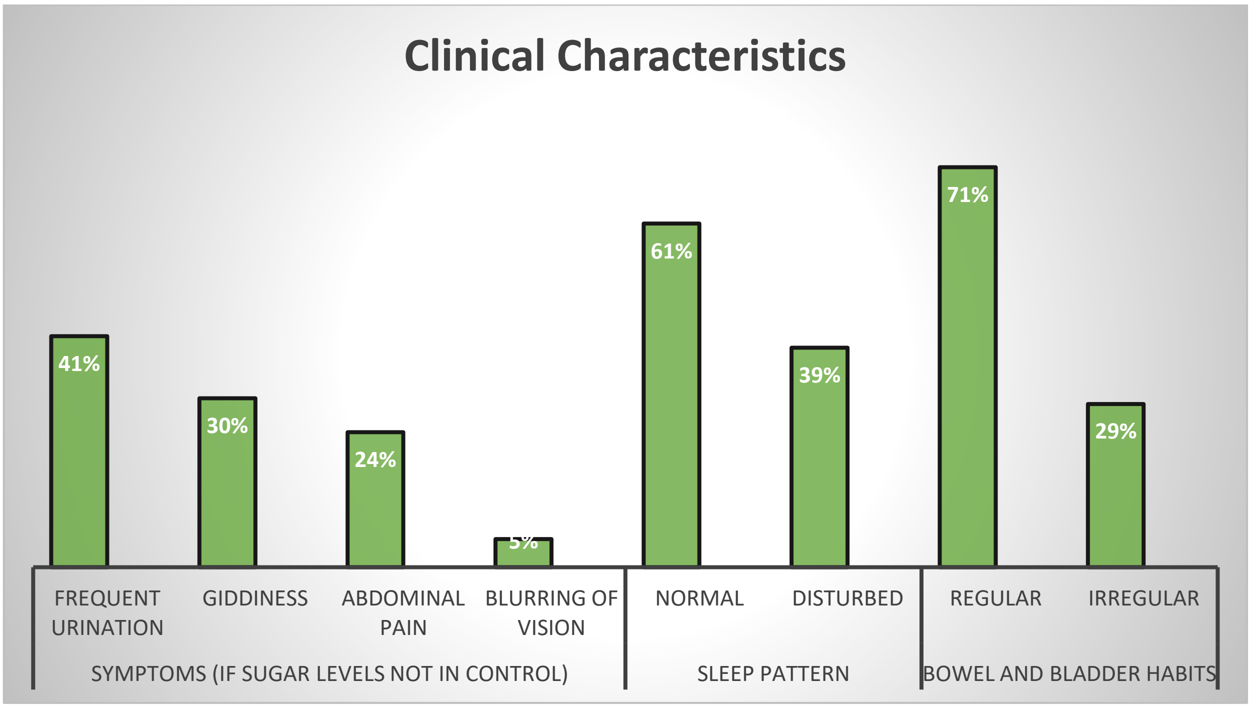


Figure.9- It provides data of symptoms associated with poorly controlled blood sugar levels among individuals, particularly those with diabetes. Frequent urination is the most prevalent symptom, reported by 41% of the respondents, followed by giddiness (30%), abdominal pain (24%), and blurring of vision (5%). Regarding sleep patterns, 61% of the surveyed individuals have a normal sleep pattern, while 39% experience disturbances. In terms of bowel and bladder habits, 71% report regular patterns, whereas 29% note irregularities. These findings highlight the prevalence of specific symptoms and their impact on daily life among individuals dealing with diabetes, underscoring the varied manifestations and challenges associated with the condition.

Figure.10. Diabetes Duration of T1DM Patients(n=114)

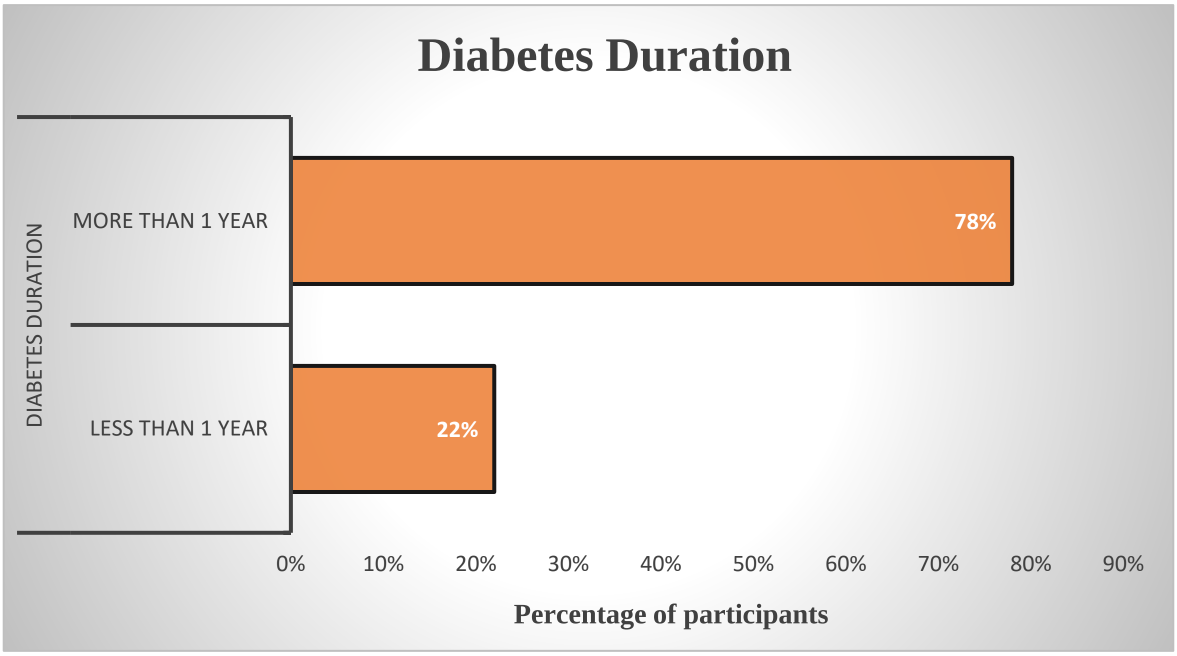


Figure.10- It shows how long people had diabetes: 25 individuals (22% of the total) were diagnosed less than a year ago, while 89 individuals (78% of the total) had diabetes for over a year. This means most people in the survey (78%) have been dealing with diabetes for a while, while a smaller group (22%) were recently diagnosed.

Figure.11. HbA1c Levels& Frequency of Insulin administration (n=114)

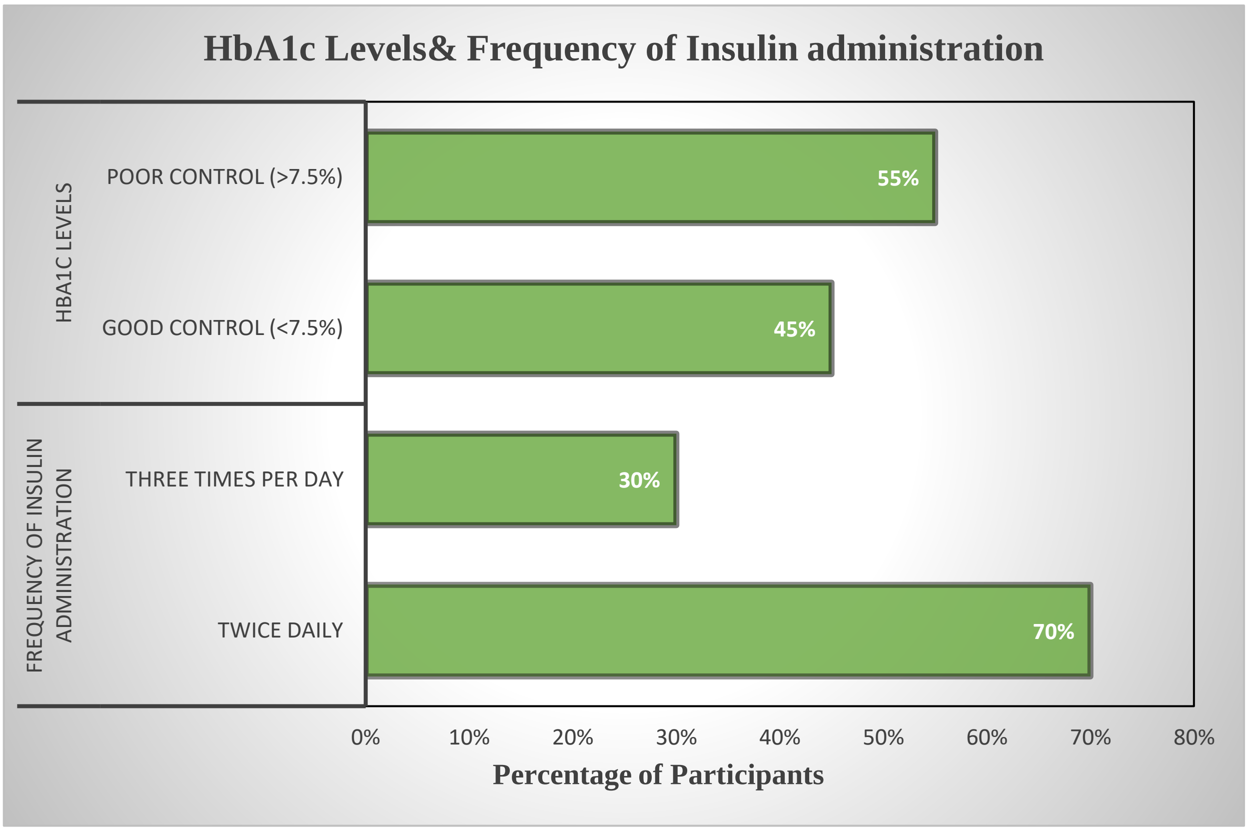


Figure.11. shows that 55% of participants have poorly controlled HbA1c levels (above 7.5%), while 45% manage to keep their levels in good control (below 7.5%). When it comes to insulin administration, 30% of the participants take their insulin three times a day, whereas a larger portion, 70%, administer it twice daily.

Figure.12. Care Givers Knowledge (n=114)

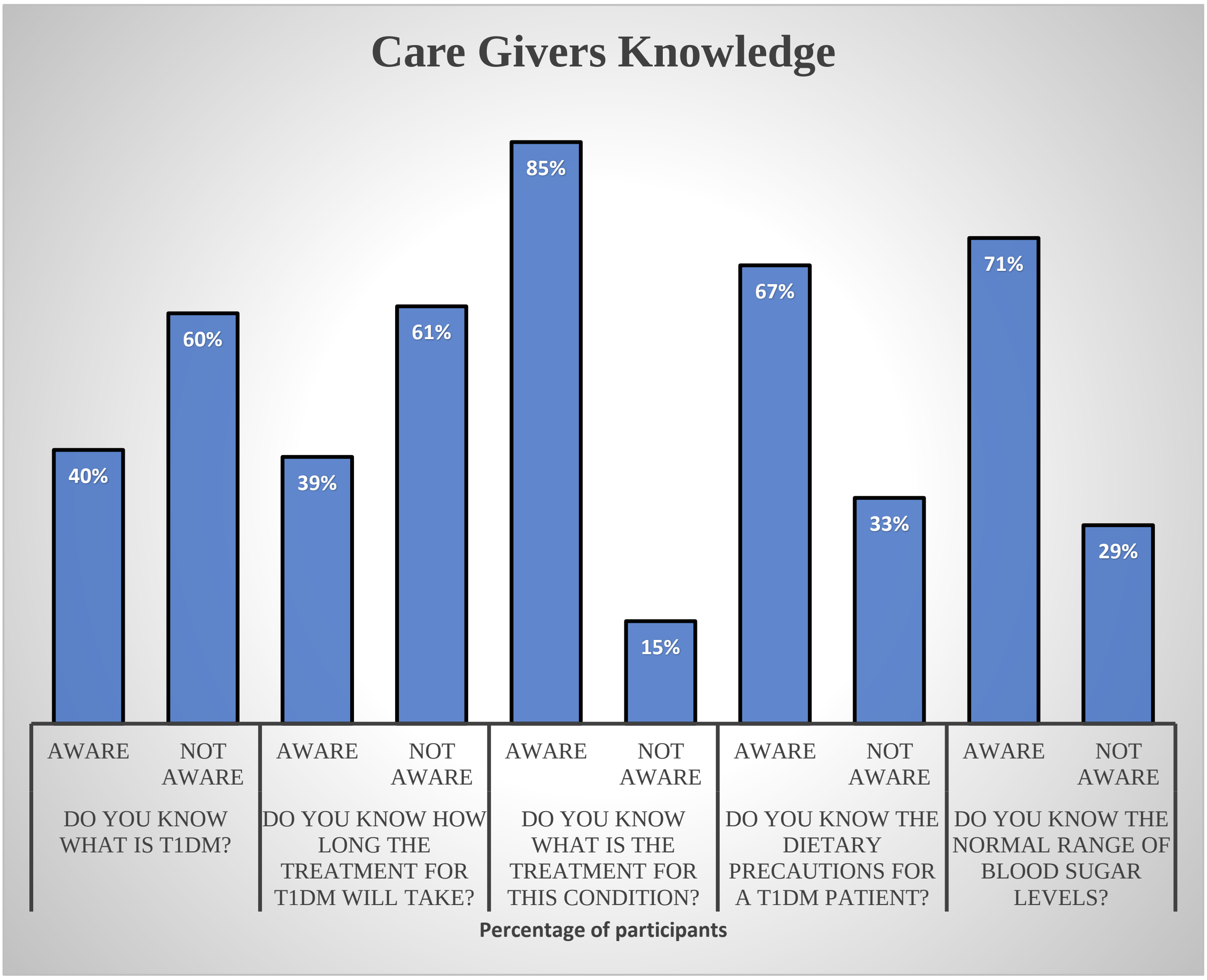


Figure.12 shows Care givers of T1DM Patients' knowledge about Type 1 Diabetes Mellitus (T1DM). It reveals that 40% know what T1DM is, while 60% do not. When asked about the treatment part how long it will take, 61% are not aware about that. A large majority, 85% knows the treatment is insulin for T1DM, with only 15% unaware. Regarding dietary precautions, 67% are knowledgeable, whereas 33% are not. Finally, 71% know the normal range of blood sugar levels, but 29% do not. This data highlights varying levels of awareness about different aspects of T1DM among Care givers of T1DM Patients.

Figure.13. Care Givers Attitude (n=114)

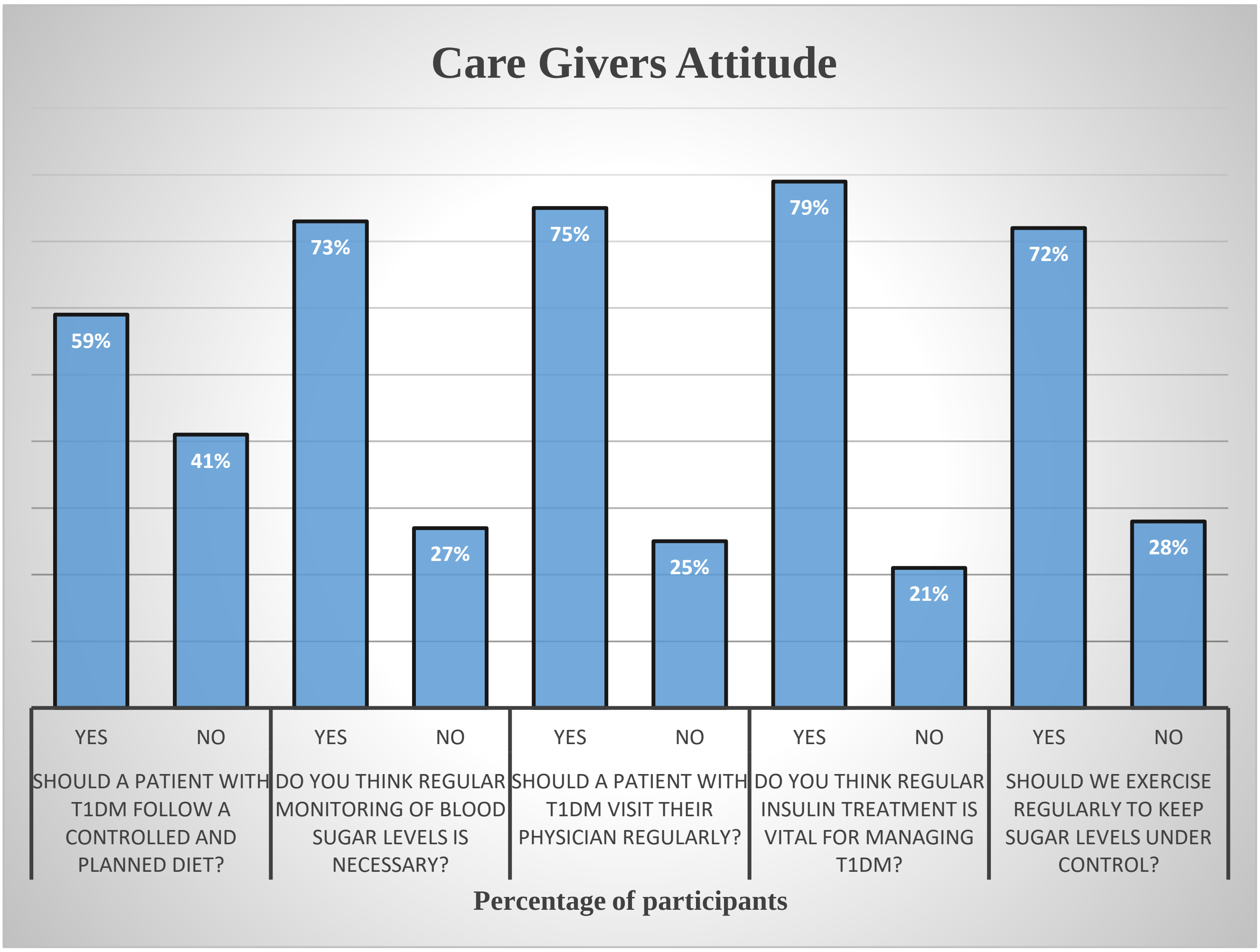


Figure.13 shows caregivers' attitudes towards managing Type 1 Diabetes (T1DM). It reveals that 59% think patients should follow a controlled diet, while 41% don't. A majority, 73%, believe regular blood sugar monitoring is necessary, with 27% disagreeing. Most caregivers, 75%, think patients should visit their doctor regularly, and 79% say regular insulin treatment is vital. Lastly, 72% believe exercise is important for controlling blood sugar, while 28% do not. This highlights caregivers' strong support for various management strategies for T1DM Patients.

Figure.14. Care Givers Practice(n=114)

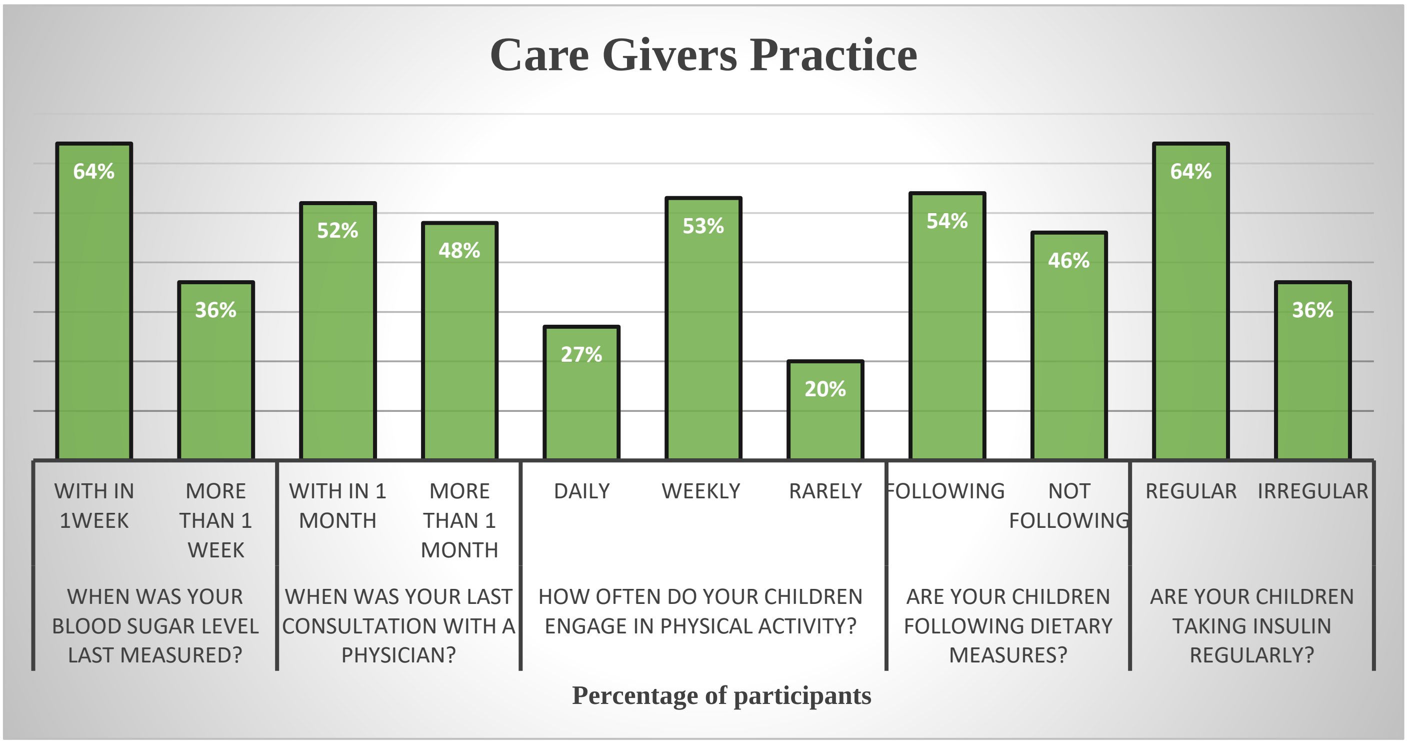
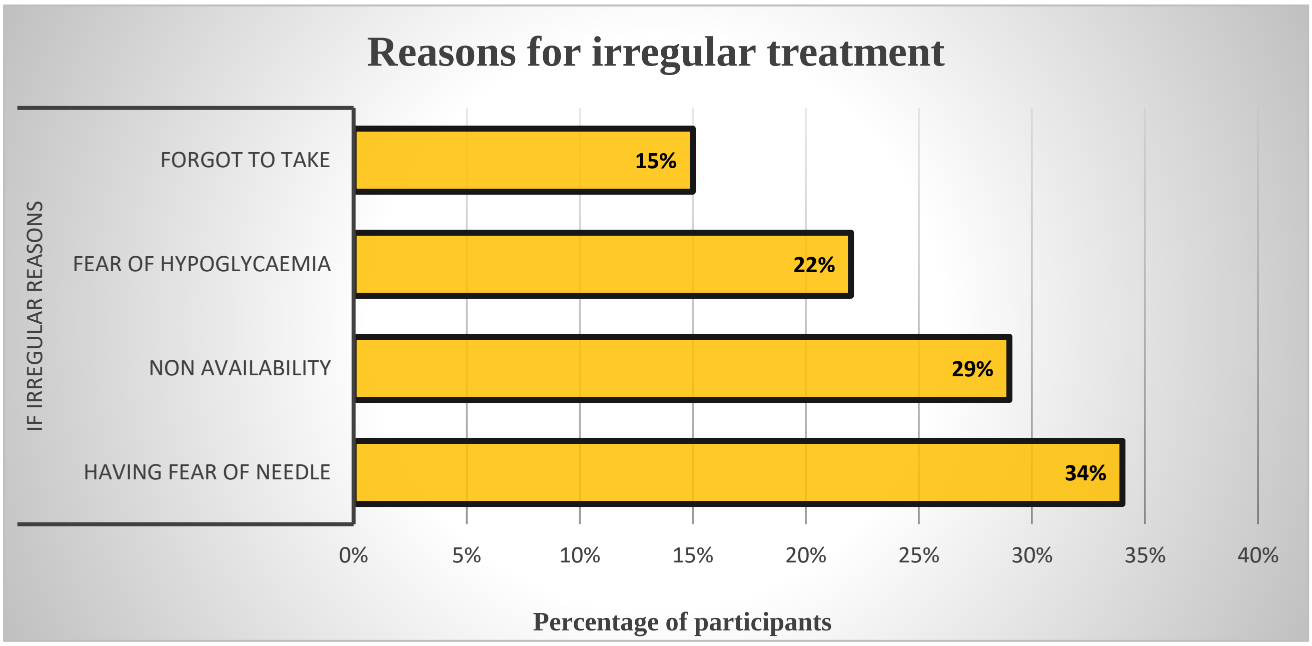
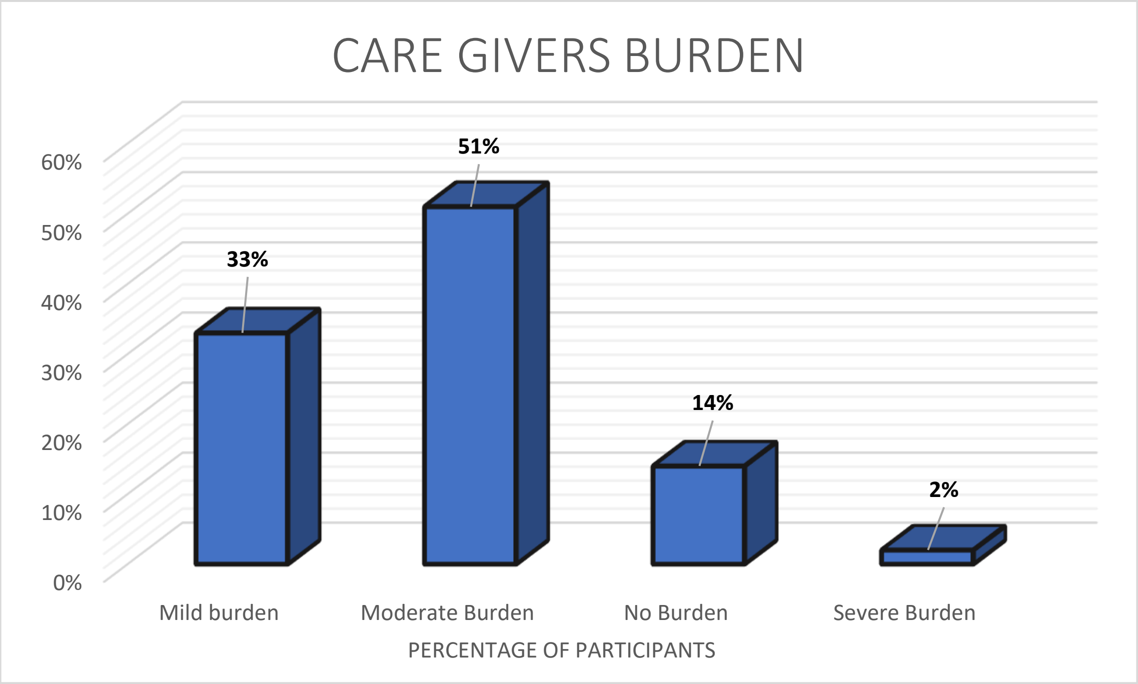


Figure.15. Reasons for irregular treatment(n=36)



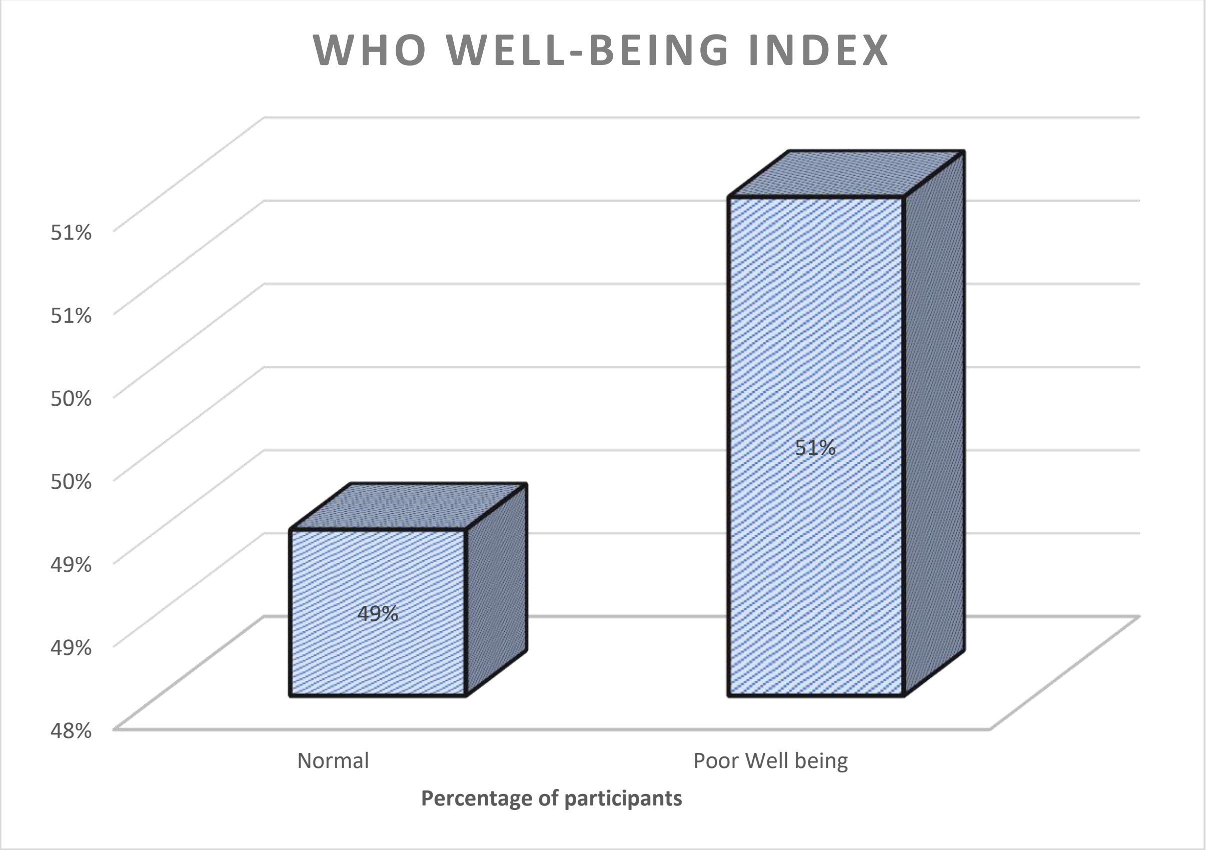
- The Figure. 14 &15 shows that 64% of children had their blood sugar measured within the last week, while 36% had it measured more than a week ago. Regarding physician visits, 52% Consulted the doctor within the last month, and 48% had not. For physical activity, 27% engage daily, 53% weekly, and 20% rarely.
- In terms of diet, 54% follow strict dietary measures, while 46% do not. Insulin is taken regularly by 64% of T1DM Patients, but 36% are irregular, with reasons including fear of needles (34%), non-availability (29%), fear of hypoglycemia (22%). This highlights the varying levels of adherence and barriers to managing diabetes.

Figure.16. CARE GIVERS BURDEN (ZBI) (n=114)



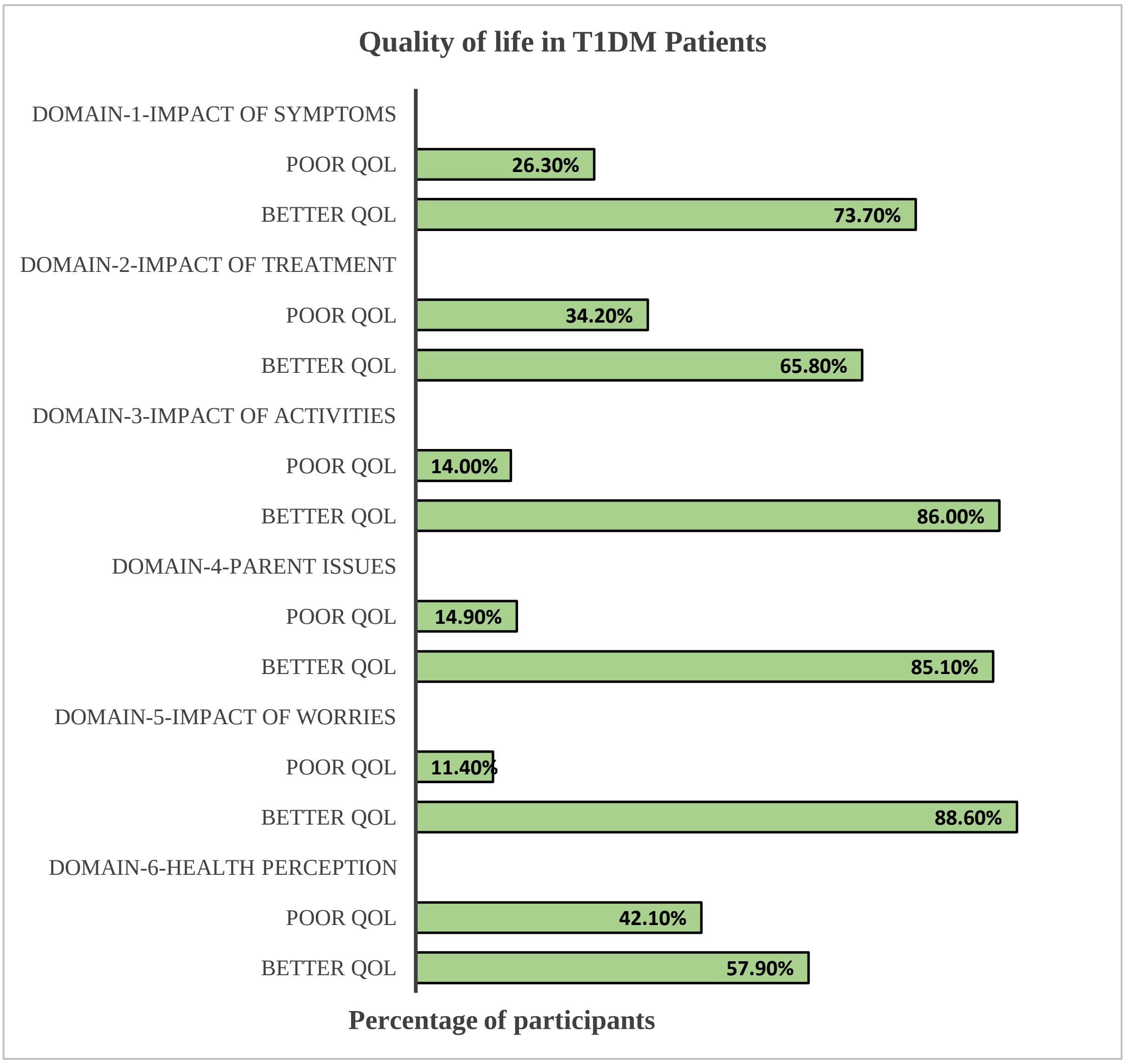
- The Figure.16 data shows the level of burden experienced by caregivers of T1DM Patients, with 33% feeling a mild burden, 51% experiencing a moderate burden and 2% facing a severe burden. This indicates that most people experience at least some level of burden, with moderate burden being the most common.

Figure.17-WHO WELL-BEING INDEX (n=114)



The Figure.17-It shows the results of the WHO Well-Being Scale, indicating that 49% of the participants have a normal well-being, while 51% have poor well-being. This suggests that slightly more than half of the participants are experiencing poor well-being.

FIGURE.18-QUALITY OF LIFE IN T1DM PATIENTS (n=114)



In Figure 18- The data illustrates various aspects of quality of life (QOL) across different domains. A significant portion of individuals report poor QOL in certain areas: 26.3% experience a negative impact from symptoms, 34.2% from impact of treatment, 14% from Impact on daily activities, 14.9% from parent-related issues, and 42.1% from health perception Domain.

Table.3. Association between Age, Gender & Diabetes duration with QOL (Impact of symptoms)

		QOL- Domain 1- Impact of symptoms		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Age	6-15 years	61	15	76	5.089	0.024*
		73%	50%	67%		
	16-25 years	23	15	38		
		27%	50%	33%		
Total		84	30	114		
		100%	100%	100%		
Gender	Female	52	15	67	1.293	0.256
		62%	50%	59%		
	Male	32	15	47		
		38%	50%	41%		
Total		84	30	114		
		100%	100%	100%		
Diabetes duration	Less than 1year	23	2	25	5.540	0.019*
		27%	7%	22%		
	More than 1 year	61	28	89		
		73%	93%	78%		
Total		84	30	114		
		100.0%	100.0%	100.0%		

*-Statistically significant

- We observed that, The Quality-of-Life Domain-1 (impact of symptoms), shows a Statistically significant association with age group of the patients at P-Value 0.024. Poor quality of life was shared equally by both age groups 6-15 years & 16-25 years.
- Among patients with poor quality of life, the Gender distribution is also equal, with 50% being both male and female, indicating that both genders are equally affected in this domain.
- Diabetes Duration is showing statistically significant association with the QOL-Domain-1(impact of symptoms) at P-Value 0.019. This suggests that the longer a person has diabetes, the more likely they were experienced a negative impact on their quality of life due to symptoms. Patients who have been living with diabetes for more than one year reported a poor quality of life (93%) compared to those who have been recently diagnosed (7%).

Table.4. Association between Mothers literacy, Type of family, SES & Residence with QOL (Impact of symptoms)

		QOL- Domain 1- Impact of symptoms		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Mothers' literacy	Illiterate/primary	66	29	95	5.211	0.022*
		79%	96%	83%		
	High school & above	18	1	19		
		21%	3%	17%		
Total		84	30	114		
		100%	100%	100%		
Type of family	Nuclear	69	26	95	0.326	0.568
		82%	87%	83%		
	Joint &3 generation	15	4	19		
		18%	13%	17%		
Total		84	30	114		
		100%	100%	100%		
SES (Socio economic status)	Class 1-3	45	12	57	1.629	0.202
		54%	40%	50%		
	Class 4 & 5	39	18	57		
		47%	60%	50%		
Total		84	30	114		
		100%	100%	100%		
Residence	Rural	49	21	70	1.270	0.260
		58%	70%	61%		
	Urban	35	9	44		
		42%	30%	39%		
Total		84	30	114		
		100%	100%	100%		

*-Statistically significant

- We observed, Quality of Life Domain-1 (impact of symptoms) it Shows statistically significant association with the mother's education level at P-Value 0.022. 96% of patients are showing poor QOL when their mother education was up to primary level. Patients tend to have poorer quality of life when their mothers had lower education levels.

- Additionally, patients in nuclear families have reported poor quality of life (87%) compared to those in joint & 3 Generation families (13%). Most of the patients from lower socioeconomic background (Class 4,5) also experience poorer quality of life (60%) in the impact of symptoms domain.
- Furthermore, patients living in rural areas (70%) reported a poor quality of life in the impact of symptoms domain compared to those in urban areas (30%).

Table.5. Association between Age, Gender & Diabetes duration with QOL (Impact of Treatment)

		QOL- Domain 2- Impact of Treatment		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Age	6-15 years	47	29	76	1.578	0.209
		63%	74%	67%		
	16-25 years	28	10	38		
		37%	26%	33%		
Total		75	39	114		
		100%	100%	100%		
Gender	Female	44	23	67	0.001	0.975
		58%	59%	59%		
	Male	31	16	47		
		42%	41%	41%		
Total		75	39	114		
		100%	100%	100%		
Diabetes duration	Less than 1year	15	10	25	0.477	0.490
		20%	26%	22%		
	More than 1 year	60	29	89		
		80%	74%	78%		
Total		75	39	114		
		100.0%	100.0%	100.0%		

- We found that there is no statistically significant association between age and the quality of life (QOL) domain related to the impact of treatment but, 74% reported poor QOL in the age group 6-15 years compared to 16-25 years (26%).

- Gender had a significant impact on this QOL domain, with 59% of females experiencing poorer quality of life compared to males. We observed Patients reported poor QOL if the diabetes duration was more than 1year (74%) compared to diagnosed with in 1 year (26%) in the impact of treatment Domain.

Table.6. Association between Mothers literacy, Type of family, SES & Residence with QOL (Impact of Treatment)

		QOL- Domain 2- Impact of Treatment		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Mothers' literacy	Illiterate/primary	62	33	95	0.070	0.791
		83%	85%	83%		
	High school & above	13	6	19		
		17%	15%	17%		
Total		75	39	114		
		100%	100%	100%		
Type of family	Nuclear	59	36	95	3.438	0.064
		79%	92%	83%		
	Joint & 3 generation	16	3	19		
		21%	8%	17%		
Total		75	39	114		
		100.0%	100.0%	100.0%		
SES (Socio economic status)	Class 1-3	41	16	57	1.910	0.167
		55%	41%	50%		
	Class 4 & 5	34	23	57		
		45%	59%	50%		
Total		75	39	114		
		100%	100%	100%		
Residence	Rural	44	26	70	0.693	0.405
		59%	67%	61%		
	Urban	31	13	44		
		41%	33%	39%		
Total		75	39	114		
		100%	100%	100%		

- We observed, Patients Reported poorer quality of life when their mothers had pre/primary education (85%) compared to high school & above. Patients from nuclear families tend to have poor QOL (92%) compared to those from joint and three-generation families (8%) in this domain impact of treatment.

- Socioeconomic status (SES) and place of residence also do not show statistically significant associations with this QOL domain. Nevertheless, poor QOL is more common among patients from lower SES classes 4 and 5 (59%) compared to those from class 1-3(41%). Similarly, patients living in rural areas report poor QOL (67%) more often than those in urban areas (33%).

Table.7. Association between Age, Gender & Diabetes duration with QOL (Impact on Activities)

		QOL- Domain 3- Impact on activities		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Age	6-15 years	69	7	76	4.399	0.036*
		70%	44%	67%		
	16-25 years	29	9	38		
		30%	56%	33%		
Total		98	16	114		
		100%	100%	100%		
Gender	Female	58	9	67	0.049	0.825
		59%	56%	59%		
	Male	40	7	47		
		41%	44%	41%		
Total		98	16	114		
		100%	100%	100%		
Diabetes Duration	Less than 1year	23	2	25	0.967	0.326
		24%	13%	22%		
	More than 1 year	75	14	89		
		76%	87%	78%		
Total		98	16	114		
		100%	100%	100%		

*-Statistically significant

- We found that Age showed statistically significant association with QOL Domain of Impact on activities at P-Value 0.036. In this domain poor QOL was reported more among the age group 16-25 years (56%) Compared to 6-15 years (44%).

- Gender not showing statistical association with QOL, as females (56%) reported poor QOL Compared to males. Patients reported poorer QOL if the diabetes duration was more than 1year (87%) compared to diagnosed with in 1 year (13%) in the impact on activities Domain.

Table.8. Association between Mothers literacy, Type of family, SES & Residence with QOL (Impact on activities)

		QOL- Domain 3- Impact on activities		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Mothers' literacy	Illiterate/primary	81	14	95	0.233	0.630
		83%	87%	83%		
	High school & above	17	2	19		
		17%	13%	17%		
Total		98	16	114		
		100%	100%	100%		
Type of family	Nuclear	79	16	95	3.722	0.054
		81%	100%	83%		
	Joint & 3 generation	19	0	19		
		19%	0%	17%		
Total		98	16	114		
		100%	100%	100%		
SES (Socio economic status)	Class 1-3	49	8	57	0.000	1.000
		50%	50%	50%		
	Class 4 & 5	49	8	57		
		50%	50%	50%		
Total		98	16	114		
		100%	100%	100%		
Residence	Rural	59	11	70	0.424	0.515
		60%	69%	61%		
	Urban	39	5	44		
		40%	31%	39%		
Total		98	16	114		
		100%	100%	100%		

- Regarding mothers' literacy, higher percentage of T1DM Patients with mothers educated up to primary level (87%) reported poor QOL compared to those whose mothers have a high education (13%), though this difference is not statistically significant.
- When considering the type of family, individuals from nuclear families reported a higher incidence of poor QOL compared to those from joint or three-generation families.
- Socioeconomic status (SES) does not show any difference in the distribution of poor QOL, as both higher SES (Class 4 & above) and lower SES (up to Class 3) groups reported 50% poor QOL, indicating no impact of SES on QOL of this Domain. Lastly, the place of residence also showed significant impact, with 69% of individuals from rural areas and 31% from urban areas reported poor QOL.

Table.9. Association between Age, Gender & Diabetes duration with QOL (Parent issues)

		QOL- Domain 4- Impact of Parent issues		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Age	6-15 years	65	11	76	0.035	0.853
		67%	65%	66%		
	16-25 YEARS	32	6	38		
		33%	35%	33%		
Total		97	17	114		
		100%	100%	100%		
Gender	Female	58	9	67	0.280	0.596
		60%	53%	59%		
	MALE	39	8	47		
		40%	47%	41%		
Total		97	17	114		
		100%	100%	100%		
Diabetes duration	Less than 1year	22	3	25	0.214	0.644
		23%	18%	22%		
	More than 1 year	75	14	89		
		77%	82%	78%		
Total		97	17	114		
		100%	100%	100%		

- We observed, age shows significant effect on QOL of this domain, with percentages of poor QOL reported among those aged 16-25 years (35%) and 6-15 years (65%). Gender shows no significant impact on QOL, with 53% of females and 47% of males reported poor QOL, indicating minimal gender disparity in the influence of parental issues on QOL.

- The Duration of diabetes shows a significant impact on QOL related to parental issues. Individuals with diabetes (82%) for more than a year reported poor QOL. These findings suggest that gender, do not significantly differentiate the quality-of-life outcomes in the context of parental issues, but diabetes duration is showing significant difference.

Table.10. Association between Mothers literacy, Type of family, SES & Residence with QOL (Parent issues)

		QOL- Domain 4- Impact of Parent issues		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Mothers' literacy	Illiterate/ primary	80	15	95	0.346	0.557
		82%	88%	83%		
	High school & above	17	2	19		
		18%	12%	17%		
Total		97	17	114		
		100%	100%	100%		
Type of family	Nuclear	80	15	95	0.346	0.557
		82%	88%	83%		
	Joint & 3 generation	17	2	19		
		18%	12%	17%		
Total		97	17	114		
		100%	100%	100%		
SES (socio economic status)	Class 1-3	51	6	57	1.728	0.189
		53%	35%	50%		
	Class 4 & 5	46	11	57		
		47%	65%	50%		
Total		97	17	114		
		100%	100%	100%		
Residence	Rural	58	12	70	0.711	0.399
		60%	71%	61%		
	Urban	39	5	44		
		40%	29%	39%		
Total		97	17	114		
		100%	100%	100%		

- We found Mothers' literacy shows significant impact on QOL, with 88% of individuals whose mothers had education up to primary level reported poor QOL compared to 11.8% of those whose mothers have a high school education or above. Similarly, the type of family showed 88% of individuals from nuclear families reported poor QOL compared to 12% from joint & three-generation families.

- Socioeconomic status (SES) and place of residence also show minimal influence on poor QOL related to parental issues. Among individuals from lower SES (Class 4 & 5), 65% reported poor QOL compared to 35% from higher SES (up to Class 3). Regarding residence, 71% of individuals from rural areas reported poor QOL compared to 29% from urban areas.

Table.11 Association between Age, Gender & Diabetes duration with QOL (worries about diabetes)

		QOL- Domain 5- Worries about diabetes		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Age	6-15 years	76	0	76	29.347	0.000*
		75%	0.0%	67%		
	16-25 years	25	13	38		
		25%	100%	33%		
Total		101	13	114		
		100%	100%	100%		
Gender	Female	60	7	67	0.147	0.701
		59%	54%	59%		
	Male	41	6	47		
		41%	46%	41%		
Total		101	13	114		
		100%	100%	100%		
Diabetes duration	Less than 1year	25	0	25	4.122	0.042*
		25%	0.0%	22%		
	More than 1 year	76	13	89		
		75%	100%	78%		
Total		101	13	114		
		100%	100%	100%		

*-Statistically significant

- We observed age group shows statistically significant association with QOL Domain of Worries about diabetes at P-Value (0.000). Among those aged 16-25 years (100%) reported poor QOL compared to none in the 6-15 years age group. This suggests that older individuals are more likely to experience a poor QOL due to worries about diabetes, whereas younger individuals appear to less impacted by them.
- We found that Females (54%) are having poorer QOL Compared to males (46%), but not statistically significant. However, the duration of diabetes shows a Statistically significant association with Domain worries about diabetes at P-Value 0.042.
- This indicates that longer duration of the disease is associated with increased worries and consequently poorer QOL. Overall, age and duration of diabetes are critical factors influencing QOL in the context of worries about diabetes, whereas gender does not significantly impact these outcomes.

Table.12. Association between Mothers literacy, Type of family, SES & Residence with QOL (worries about diabetes)

		QOL- Domain 5- Worries about Diabetes		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Mothers' literacy	Illiterate/primary	82	13	95	2.935	0.087
		81%	100%	83%		
	High school & above	19	0	19		
		19%	0.0%	17%		
Total		101	13	114		
		100%	100%	100%		
Type of family	Nuclear	84	11	95	0.017	0.895
		83%	85%	83%		
	Joint & 3 generation	17	2	19		
		17%	15%	17%		
Total		101	13	114		
		100%	100%	100%		
SES (Socio economic status)	Class 1-3	47	10	57	4.254	0.039*
		46%	77%	50%		
	Class 4 & 5	54	3	57		
		54%	23%	50%		
Total		101	13	114		
		100%	100%	100%		
Residence	Rural	63	7	70	0.354	0.552
		62%	54%	61%		
	Urban	38	6	44		
		38%	46%	39%		
Total		101	13	114		
		100%	100%	100%		

*-Statistically significant

- We observed Mothers' literacy Shows significant impact on QOL of T1DM Patients, with 88% of individuals whose mothers have education up to pre/primary level reported poor QOL compared to those whose mothers had higher education (12%). Similarly, the type of family showed 85% of individuals from nuclear families reported poor QOL compared to 15% from joint & three-generation families.

- Socioeconomic status (SES) shows a Statistically significant association with QOL Domain worries about diabetes at P-Value 0.039. Most of the Patients from Higher SES (up to Class 3) reported poor QOL (77%) compared to those from lower SES (23%).

Table.13. Association between Age, Gender & Diabetes duration with QOL (Health Perception)

		QOL-Domain 6-Health Perception		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Age	6-15 years	49	27	76	4.048	0.044*
		74%	56%	67%		
	16-25 years	17	21	38		
		26%	44%	33%		
Total		66	48	114		
		100%	100%	100%		
Gender	Female	40	27	67	0.218	0.641
		61%	56%	59%		
	Male	26	21	47		
		39%	44%	41%		
Total		66	48	114		
		100%	100%	100%		
Diabetes Duration	Less than 1year	20	5	25	6.419	0.011*
		30%	10%	22%		
	More than 1 year	46	43	89		
		70%	90%	78%		
Total		66	48	114		
		100%	100%	100%		

*-Statistically significant

- We observed, age shows statistically significantly association with Domain health perception, with 44% of individuals aged 16-25 years reported poor QOL compared to 56% of those aged 6-15 years (p = 0.044).

- However, the duration of diabetes significantly affects health perception, with 90% of individuals who had diabetes for more than a year reported poor QOL, compared to only 10% of those with diabetes for less than a year, its showing statistically significant association at P-Value 0.011. This indicates that a longer duration of diabetes is strongly associated with negative health perceptions, which in turn negatively impact QOL.

Table.14. Association between Mothers literacy, Type of family, SES & Residence with QOL (Health Perception) `

		QOL- Domain 6- Health Perception		Total	Chi-square Value	P-Value
		Better QOL (below 50)	Poor QOL (50& above)			
Mothers' literacy	Illiterate/primary	52	43	95	2.332	0.127
		79%	90%	83%		
	High school & above	14	5	19		
		21%	10%	17%		
Total		66	48	114		
		100%	100%	100%		
Type of family	Nuclear	51	44	95	4.145	0.042*
		77%	92%	83%		
	Joint & 3 generation	15	4	19		
		23%	8%	17%		
Total		66	48	114		
		100%	100%	100%		
SES (Socio economic status)	Class 1-3	34	23	57	0.144	0.704
		52%	48%	50%		
	Class 4 & 5	32	25	57		
		48%	52%	50%		
Total		66	48	114		
		100%	100%	100%		
Residence	Rural	39	31	70	0.354	0.552
		59%	65%	61%		
	Urban	27	17	44		
		41%	35%	39%		
Total		66	48	114		
		100%	100%	100%		

*-Statistically significant

- We found that, where mothers educated up to pre/primary level, where patients report a higher incidence of poor QOL (90%) compared to those with mothers having high school education or above (10%), although this difference is not statistically significant. This suggests that lower maternal literacy may be associated with poorer health perception and thus poorer QOL.

- We observed, Type of family is showing statistically significant association with QOL Domain of health perception at P-Value 0.042, with those from nuclear families reported a higher percentage of poor QOL (92%) compared to those from joint or three-generation families (8%). This indicates that nuclear family settings might contribute to poorer health perception.

Table.15- Association between Age, Gender & Diabetes duration with Well-being of patient

		WHO WELL-BEING INDEX				**P-Value**
		Normal (13 & more)	**Poor Well Being(below 13)**	**Total**	**Chi-square Value**	
Age	6-15 years	41	35	76	2.123	0.145
		73%	60%	67%		
	16-25 years	15	23	38		
		27%	40%	33%		
Total		56	58	114		
		100%	100%	100%		
Gender	Female	30	37	67	1.229	0.268
		54%	64%	58%		
	Male	26	21	47		
		46%	36%	42%		
Total		56	58	114		
		100%	100%	100%		
Diabetes duration	Less than 1year	17	8	25	4.566	0.033*
		30%	14%	22%		
	More than 1 year	39	50	89		
		70%	86%	78%		
Total		56	58	114		
		100%	100%	100%		

*-Statistically significant

- We found that 60% reported poor well-being among age group 6-15 years compared to 16-25 years. Similarly, 64% of females reported poorer QOL compared to males (36%).

- We observed, Diabetes duration showing statistically significant association with the well-being at P-Value of 0.033. Poor well-being is more among the patients who are suffering from T1DM more than a year (86%) compared to recently diagnosed patients.

Table.16 Association between Mothers literacy, Type of family, SES & Residence with Wellbeing of patient

		WHO WELL-BEING INDEX			**Chi-square Value**	**P-Value**
		Normal (13 & more)	**Poor Well Being (below 13)**	**Total**		
Mothers' literacy	Illiterate/primary	45	50	95	0.702	0.402
		80%	86%	83%		
	High school & above	11	8	19		
		20%	14%	17%		
Total		56	58	114		
		100%	100%	100%		
Type of family	Nuclear	46	49	95	0.112	0.738
		82%	84%	83%		
	Joint & 3 generation	10	9	19		
		18%	16%	17%		
Total		56	58	114		
		100%	100%	100%		
SES (Socio economic status)	Class 1-3	29	28	57	0.140	0.708
		52%	48%	50%		
	Class 4 & 5	27	30	57		
		48%	52%	50%		
Total		56	58	114		
		100%	100%	100%		
Residence	Rural	36	34	70	0.386	0.535
		64%	59%	61%		
	Urban	20	24	44		
		36%	41%	39%		
Total		56	58	114		
		100%	100%	100%		

- We observed Mothers literacy statistically not significant with well-being in patients. Poor well-being (86%) was more common among the mothers who are having lesser education. Patients in nuclear families (84%) tend to have worse well-being compared to those in joint or three-generation families.

- Additionally, families with lower socioeconomic status (52%) have more patients with poor well-being compared to those with higher socioeconomic status. Furthermore, patients living in rural areas (59%) with Type 1 Diabetes Mellitus (T1DM) have poorer well-being than those living in urban areas (41%).

Table.17 Association between Age, Gender & Diabetes duration with Caregivers Burden

		Caregivers Burden (Zarit burden Interview)					Chi-square Value	P-Value
		No burden (0-21)	Mild burden (21-40)	Moderate burden (41-60)	Severe burden (61-88)	Total		
Age	6-15 years	12	18	44	2	76	10.075	0.018*
		75%	47%	76%	100%	67%		
	16-25 years	4	20	14	0	38		
		25%	53%	24%	0.0%	33%		
Total		16	38	58	2	114		
		100%	100%	100%	100%	100%		
Gender	Female	7	20	39	1	67	3.862	0.277
		44%	53%	67%	50%	59%		
	Male	9	18	19	1	47		
		56%	47%	33%	50%	41%		
Total		16	38	58	2	114		
		100%	100%	100%	100%	100%		
Diabetes duration	Less than 1year	6	5	13	1	25	4.902	0.179
		37%	13%	22%	50%	22%		
	More than 1 year	10	33	45	1	89		
		63%	87%	78%	50%	78%		
Total		16	38	58	2	114		
		100%	100%	100%	100%	100%		

*Statistically significant

- We observed Significant difference in caregiver burden based on age group of T1DM Patient. Caregivers of children aged 6-15 with Type 1 Diabetes are facing moderate (76%) and severe (100%) levels of burden, compared to those caring for patients aged 16-25 years. Age group is showing statistically significant association with Care givers Burden at P-value of 0.018.

- There is no statistical association between caregiver burden and the patient's gender. However, caregivers of female patients experience mild (53%) and moderate (67%) burden more than those of male patients. Additionally, caregivers report higher levels of mild (87%) and moderate (78%) burden when the patient had diabetes for more than a year, compared to those caring for recently diagnosed patients.

Table.18-Association between Mothers literacy, Type of family, SES & Residence with Caregivers burden.

		Caregivers Burden (Zarit burden Interview)					Chi-square Value	P-Value
		No burden (0-21)	Mild burden (21-40)	Moderate burden (41-60)	Severe burden (61-88)	Total		
Mothers Literacy	Illiterate/primary	9	33	51	2	95	10.070	0.018*
		56%	87%	88%	100%	83%		
	High school & above	7	5	7	0	19		
		44%	13%	12%	0.0%	17%		
Total		16	38	58	2	114		
		100%	100%	100%	100%	100%		
Type of family	Nuclear Family	13	36	44	2	95	6.339	0.096
		81%	95%	76%	100%	83%		
	Joint & 3 Generation Family	3	2	14	0	19		
		19%	5%	24%	0.0%	17%		
Total		16	38	58	2	114		
		100%	100%	100%	100%	100%		
SES (Socio economic status)	Class 1-3	9	22	26	0	57	4.902	0.179
		56%	58%	45%	0.0%	50%		
	Class 4 & 5	7	16	32	2	57		
		44%	42%	55%	100%	50%		
Total		16	38	58	2	114		
		100%	100%	100%	100%	100%		
Residence	Rural	9	23	36	2	70	1.460	0.692
		56%	61%	62%	100%	61%		
	Urban	7	15	22	0	44		
		44%	39%	38%	0.0%	39%		
Total		16	38	58	2	114		
		100%	100%	100%	100%	100%		

*Statistically significant

- We found a statistically significant association between mothers' literacy levels and caregiver burden at P-Value 0.018. Caregivers with lower education levels (pre-primary or primary) reported experiencing moderate (88%) & severe (100%) burdens. Those in nuclear families faced moderate (76%) & severe (100%) burdens compared to those in joint or three-generation families.

- Severe burden was reported among more number of caregivers from lower socio-economic classes (4 and 5) compared to those from higher classes (1 to 3). Similarly, caregivers in rural areas experienced more severe burden (100%) compared to their urban counterparts.

Table.19- Binary Logistic Regression of QOL, WHO -Wellbeing index, and Caregivers burden with independent variables

Independent variables		Odds ratio	Confidence interval	Wald test	P-value
QOL-Domain 1-Impact of symptoms					
Age	6-15 years	1.673	0.663-4.225	1.186	0.024*
	16-25 years	1			
Diabetes duration (years)	Less than 1 year	0.257	0.052-1.265	2.793	0.019*
	More than 1 year	1			
Mothers' literacy	Illiterate/primary	0.150	0.019-1.203	3.192	0.022*
	High school& above	1			
QOL-Domain 3-Impact of activities					
Age	6-15 years	2.621	0.878-7.823	2.982	0.036*
	16-25 years	1			
QOL-Domain 5-Impact of worries					
Socio economic status (SES)	Class 1-3	0.450	0.099-2.054	1.063	0.039*
	Class 4& 5	1			
QOL-Domain 6-health perception					
Age	6-15 years	0.681	0.287-1.614	0.761	0.044*
	16-25 years	1			
Diabetes duration	Less than 1 year	0.332	0.106-1.039	3.590	0.011*
	More than 1 year	1			
Type of family	Nuclear	2.811	0.840-9.411	2.810	0.042*
	Joint&3-Generation family	1			
Caregivers Burden (Zarit burden Interview)					
Age	16-25 years	0.841	0.236-2.993	0.071	0.018*
	6-15 years	1			
Mothers' literacy	Illiterate & pre/primary	5.387	1.652-17.562	7.800	0.018*
	High school above	1			
WHO-Wellbeing Index					
Diabetes Duration(years)	Less than 1 year	0.367	0.144-0.939	4.377	0.033*
	More than 1 year	1			

*-Statistically significant

- Binary logistic regression was applied to the independent variables that showed a significant association with the Quality of life (QOL), well-being of T1DM Patients & Caregivers burden. The analysis revealed that individuals aged 6-15 years have a 1.6 times higher risk compared to those aged 16-25 years in the QOL domain Impact of symptoms. In the domain Impact of activities, the 6-15 years age group has a 2.6 times higher risk than the 16-25 years age group.

- Additionally, in the QOL domain of health perception, individuals from nuclear families are having 2.8 times more risk compared to those from joint & three-generation families. However, all these findings were statistically insignificant in the binary logistic regression analysis.

- In the caregiver’s burden analysis, Mothers with lower education (Illiterate & Primary school) are having 5 times more risk compared to the higher education (high school & above) and its findings were statistically significant in the binary logistic regression.

Coping Strategies explained to Caregivers:

As per our study objective all the primary caregivers were explained about coping strategies to manage the stress related to T1DM Patient care. Coping strategies were framed by consulting experts and were explained to primary caregivers after interview.

Following coping strategies were explained:

Condition Acceptance: Understand and accept that managing T1DM is a lifelong process. Acceptance can help caregivers approach daily tasks with a positive and proactive mindset.

Establish a Routine: Develop a consistent daily schedule for meals, blood sugar monitoring, and insulin administration. A routine helps in maintaining stable blood sugar levels and reduces stress for both the caregiver and the child.

Planning Ahead: Plan meals, activities, and insulin doses in advance to avoid last-minute complications. Being prepared helps in managing unexpected changes and maintaining effective diabetes control.

Seeking Social Support: Connect with other caregivers, support groups, or online forums to share experiences and advice. Social support can provide emotional relief and practical tips for better diabetes management.

Emotional Support from Family & Friends: Encourage family and friends to provide emotional backing and practical help. Having a strong support system can alleviate the caregiver’s stress and improve overall well-being.

Healthy Communication with Healthcare Providers: Maintain regular and open communication with healthcare professionals for guidance and updates. Effective communication ensures that caregivers have the necessary information to manage the condition well.

Emergency Preparedness: Keep emergency supplies, like glucagon kits and extra insulin, readily available. Being prepared for emergencies can prevent serious complications and ensure quick response during a crisis.

Monitoring and Record Keeping: Keep detailed records of blood sugar levels, insulin doses, meals, and physical activities. Regular monitoring and record-keeping help in identifying patterns and making informed decisions about diabetes management.

Flexibility and Adaptation:

Be ready to adjust routines and management plans as needed to accommodate changes in the child's condition. Flexibility ensures that caregivers can respond effectively to varying diabetes care needs.

Overcoming Barriers of Insulin Shortage:

Stay informed about local and national resources for obtaining insulin and supplies during shortages. Establishing a network with healthcare providers and pharmacies can help in finding alternative solutions during supply disruptions.

At the end caregivers were thanked for their participation.

DISCUSSION:

This study aimed to Assess the Quality of life (QOL) of Type 1 Diabetes Mellitus (T1DM) patients and the caregiver's burden in the Vijayapura district. Our research sought to address the specific challenges faced by T1DM patients and their caregivers.

Studies Carried out in different regions globally and in India have shown differing levels of QOL impairment and caregiver burden, influenced by socioeconomic status, healthcare access and attitude towards chronic illness. These differences can be attributed to the varying methodologies and scales used to estimate QOL and Caregivers burden. By focusing on Vijayapura district, our study provides valuable insights into T1DM Patients life in this district, underscoring the need for personalized interventions to improve QOL and reduce caregiver's burden.

Sociodemographic Profile of study participants:

Majority of the participants (45%) were in the 11-15 years age group in our study. Mary AM et.al.,2017 Conducted a longitudinal study in United States observed the incidence rate of T1DM was greatest in youth aged 10–14 years,[65] this finding suggests the most common age group when T1DM People are diagnosed and we observed similar in our study. Gang b et.al., in their review article (2024) also observed similar trend globally, that incidence of T1DM being more Common among the adolescents age group (10-14).[66]

In our study majority of the T1DM Patients (61%), were from rural areas, Getachew Gebremedhin et.al.,2020 conducted a study in urban and rural areas to see the differences of T1DM and showed , both increasing incidence in rural areas from 1.2 to 2.6 per 1000 adult compared to urban incidence increase from 1.0 to 2.2 per 1000 adult residents.[67] It is an indication that T1DM is not only urban disease, now it is increasing even to rural areas may be due to better access to care & diagnosis.

Study conducted by Sze M Ng et.al.,2023 in England and Wales from 2017 to 2022 shows that the incidence of T1DM was higher among males compared to females.[68] But in our study the most of the T1DM Patients were females compared to males. This may be due to geographical variation, population demographics and local environmental factors.[69]

Clinical characteristics:

In our study frequent urination was most common symptom mentioned by T1DM Patients, which is one of the main symptoms of T1DM. Cleveland clinic Mentions frequent urination as the common symptom& it occurs due to the body inability to use insulin to break down glucose and it makes more urine to get rid of it.[70]

We observed a significant number of T1DM patients experiencing sleep disturbances in our study. Michelle M. Perfect et.al.,2020 conducted a cross-sectional study highlighting the prevalence of inadequate sleep duration and disturbances among T1DM patients.[71] Similarly, Mi Kyoung et.al.,2023 in their cross-sectional study in South Korea, found that depression and the duration of the disease notably impact sleep latency, duration, and disturbances, frequent urination, and potentially due to increased psychological stress and anxiety.[72]

Almost 55 % of the patients are having poor glycemic control with higher HbA1c Levels (>7.5%) in our study. Similar findings were observed in the study conducted by Hanaa A. Mohammad et.al.,2012 reasons may be due to the longer diabetes duration, poor treatment adherence & poor dietary precautions.[73]

Well-being of T1DM Patients:

Poor Well-being was more among the female patients in our study compared to males. similar findings were observed in study conducted by Kathryn M. King et.al.,2017 in North East region of UK. One of the major findings, female patients were responded that, they said it was annoying; it was intrusive, interfered with their life, and imposed restrictions on them (Barrier's category). Diabetes made them feel different from their friends and got them down.[74]

The study conducted by Mohammed Najeeb Ashraf et.al.,2024 in Canada among T1DM Patients about Emotional, Psychological and Social Well-being stated that People with T1DM over a longer duration are more likely to suffer from poor well-being, mental health issues such as, frequent mood changes, low self-esteem, anxiety, depression.[75] In our study similar results were found as diabetes duration showed statistically significant association with the well-being of the patient.

Quality of life in T1DM Patients:

The "Impact of Symptoms" domain assesses how the physical symptoms of Type 1 Diabetes Mellitus (T1DM) affect a person's daily life, including: Missed School/Work, Poor Sleep Quality & Physical Illness. The "Impact of Treatment" domain assesses how the treatment regimen for Type 1 Diabetes Mellitus (T1DM) affects a person's daily life, including: Diabetes Interference, Diet Restriction & Pain Associated with the Treatment.

The "Impact on Activities" domain in the context of Type 1 Diabetes Mellitus (T1DM) specifically addresses about the interfere with the by cycling, school activities and limiting friendships. Parent issues domain discusses about the worries of their parents about their future. Domain on worries discussed about the all worries related to marriage, children, job & complications. Health perception domain mainly focused on comparison of health among same age groups.

Our study results showed that lower maternal education and socioeconomic status are linked to a poorer quality of life (QOL) among patients with Type 1 Diabetes Mellitus (T1DM). Similarly, research conducted in Saudi Arabia by Jumanah A Alhaddad et.al.,2023 found that higher family socioeconomic status and elevated parental education levels, especially among mothers, correlate significantly with higher overall QOL scores.[76] Higher maternal education and socioeconomic status are crucial because they contribute to better health literacy and access to resources, enabling more effective care and management of T1DM.

We observed that female patients experience a lower quality of life compared to male patients, particularly in the domain of 'impact of worries' in our study. This finding aligns with the results of a study by Ana María Castellano-Guerrero et.al.,2020 which indicated that female patients not only had a lower overall quality of life than males but also scored significantly worse on the diabetes-related worries subscale.[77] This disparity may be attributed to the increased emotional burden and stress that women often face when managing chronic illnesses.

Our study found a statistically significant association between the duration of diabetes and quality of life (QoL) in most domains, with longer diabetes duration linked to poorer QoL. Similarly, Richard R. Rubin et.al.,1999 observed that an increased duration of diabetes is associated with decreased QoL.[78]

Zainab Al-Abadla et.al.,2022 also reported consistent findings, showing that a longer duration of diabetes correlates with poorer health-related quality of life (HRQoL). One of the reasons for this could be the cumulative physical and emotional burden of managing diabetes over a prolonged period.[79]

In our study, Type 1 Diabetes Mellitus (T1DM) patients from nuclear families reported very poor quality of life (QoL) across all domains, possibly due to lack of support system. Melissa Cousino et.al.,2013 emphasized the significance of family involvement in T1DM care, noting that shared caregiving responsibilities lead to better outcomes. They observed that family involvement, particularly from parents and other relatives, positively impacts children's health and psychosocial well-being.[80]

Care givers Knowledge Attitude & Practice (KAP):

In our study, we observed that some of the caregivers were not fully aware about the necessity of lifelong insulin administration and the dietary precautions required for their children. Bernard Afriyie Owusu et.al.,2023 conducted research on the knowledge levels of caregivers of T1DM patients and found significant gaps in their knowledge.[84] These gaps were particularly pronounced in areas such as carbohydrate counting, managing severe hypoglycemia, and handling the insulin administration. These Gaps in knowledge may be attributed to the caregivers' lower educational status.[81]

When asked practice 50% of the caregivers told their children are not consulting the doctor & not following the diet properly. Only one fourth(1/4th) of the patients in our study are involved in physical activity in their day today activities. Similar findings were discussed in the study conducted by Jothydev Kesavadev et.al.,2014 about diet and physical activity, it was observed that nutrition of the T1DM patients was compromised, due to fears and misconceptions. Parents restricted the exercise and outings of the children due to fear of hypoglycemia.[82]

Our study identified fear of needles, fear of hypoglycemia, and non-availability of insulin as primary reasons for irregular insulin administration in individuals with T1DM. These findings are consistent with existing literature, reinforcing the complexity of insulin adherence in T1DM management. A study by Jothydev Kesavadev et.al.,2014 Similarly highlighted these barriers, particularly emphasizing the impact of inadequate healthcare infrastructure in rural areas. A significant proportion (61%) of our study population resided in rural areas, where insulin availability is often a critical challenge, impeding consistent treatment and achievement of glycemic control goals. This scarcity in rural healthcare settings exacerbates the difficulty in managing T1DM effectively.[82]

Additionally, fear of insulin injections is a considerable barrier, as demonstrated in a survey conducted by Peyrot M et.al.,2010 where 33% of patients reported a fear of insulin injections. This apprehension can significantly deter patients from adhering to their prescribed insulin regimen, leading to suboptimal disease management.[83] Fear of hypoglycemia also plays a substantial role in the irregular administration of insulin. Our study also showed fear of hypoglycemia as a reason for irregular insulin administration According to a study by Gonder-Frederick LA et al.,2006 patients who frequently experience hypoglycemic episodes develop anxiety and concern about these episodes, often resulting in deliberate underuse or avoidance of insulin to prevent further occurrences.[84]

Care Givers Burden:

In this study zarit burden interview was used, which measures the burden experienced by caregivers. It explores discomfort in social situations due to the caregiving role, perceived expectations from the relative, financial strain, concerns about long-term caregiving capabilities, loss of personal control, uncertainty about caregiving decisions, feelings of inadequacy in caregiving, and the overall sense of burden. Each item captures a specific aspect of the multifaceted stress and challenges faced by caregivers**.**

In our study, 33% experience a mild burden, and majority 53% experienced moderate to severe burden. In contrast, research conducted by Lourdes Balcázar-Hernández et.al.,2023 in Mexico revealed that 19% of caregivers had a mild burden, while 14% experienced a severe burden.[62] The variation in Care givers burden percentages may be attributed to differences in healthcare systems, social support networks, disease characteristics, geographical locations & adaptation of the scale used.

Our study found that caregiver burden is higher among younger T1DM patients aged 6-15 years and for mothers with lower education levels. Similar results were reported by Kobos et.al.,2023 In their research conducted across four pediatric clinics in Poland. This trend may be due to the increased care demands and complexities of managing T1DM in younger children, which can be particularly challenging for mothers with less educational background, potentially due to limited access to resources, knowledge, and coping strategies.[61]

In our findings, we observed that caregivers in nuclear families have more burden compared to those in joint families. Similar findings observed according to a scoping review by Tara Azimi et al.,2024 parents of children with T1DM often experience loneliness in their caregiving roles. The study emphasizes the beneficial role of peer support among these parents.[85] For instance, parents felt like It's reassuring to have someone to converse with and share the responsibilities of caring for T1DM patients. These findings reinforce our conclusion that caregivers in nuclear families encounter greater difficulties.[85]

SUMMARY

This was a Cross-sectional study conducted in Vijayapura district, North Karnataka, aimed to assess the Quality of life (QOL) and Well-being in Type 1 Diabetes Mellitus (T1DM), Knowledge, attitude & Practice of caregivers towards T1DM and caregiver burden among primary care givers. Study utilized a structured interview approach with a pre-tested questionnaire to gather data and HbA1c was measured using onsite testing kit. The study was conducted in three major hospitals that served T1DM cases from all over the district.

Major findings:

- We found that most of the Primary caregivers were mothers (75%), and the majority (84%) were nuclear families. A significant proportion of patients resided in rural areas (61%). The predominant age group among T1DM patients was 11-15 years (45%) and Hindu by religion (91%) with a notable representation from the OBC category (41%).
- Most common clinical symptoms found among T1DM patients were, frequent urination (41%), giddiness (30%), and abdominal pain (24%). Sleep patterns were reportedly disturbed in 39% of patients, and 29% had irregular bowel and bladder habits.
- The majority of patients (78%) had been diagnosed with diabetes for more than a year. In terms of T1DM control, 55% of patients had poorly controlled HbA1c levels (>7.5%), and 30% required insulin thrice daily.

The Quality-of-life (Domains wise) of T1DM Patients

- Impact of Symptoms: 26.3% of people feels that their symptoms significantly lowered their quality of life.
- Impact of Treatment: 34% of individuals found that the treatments they undergo have a major negative effect on their quality of life.
- Impact on Daily Activities: 14% reported that their daily activities are greatly disrupted, reducing their overall quality of life.

- Parent-Related Issues: 15% experienced poor quality of life due to challenges related to parenting.
- Health Perception: 42% had a negative view of their overall health, which greatly impacts their quality of life.
- In the impact of symptoms domain, diabetes duration & Mothers' literacy was found statistically associated with the Quality of life (QOL). Majority (93%) of T1DM Patients with Diabetes duration more than one year reported poorer quality of life compared to those diagnosed with in a year.
- In the impact of activities domain, age group and quality of life were statistically associated. Poor QOL was reported more among the age group 16-25 years (56%) compared to 6-15 years.
- In the domain of worries about the diabetes, the Age group and Diabetes duration were found to be statistically associated with the Quality of life (QOL). In the Health perception domain statistically, significant association was found between the type of family and Quality of life.
- WHO well-being screening for T1DM, showed that 51% of the participants had a poor well-being score. Diabetes duration was found statistically associated with Well-being of the patient. Poor well-being is more common among the patients who have been suffering from T1DM for more than a year (86%) compared to those diagnosed with in a year.
- About the knowledge among the caregivers, 61% not aware about treatment duration, 33% not aware about the proper dietary precautions to be taken & 29% told they don't know the normal range of blood sugar levels. In the attitude towards TDM care ,75% think patient should visit physician regularly & 27% did not think regular blood sugar monitoring is required.

- In the Care givers burden, 51% experienced a moderate burden and 33% felt mild burden. Age group of patients showed statistically significant association with the caregiver’s burden. Mothers caring for younger patients (aged 6-15 years) experienced higher levels of burden, compared to these caring for older patients (aged 16-25 years).
- We observed Mothers’ literacy showed statistically significant association with Caregivers Burden. Mothers with lower education levels (illiterate/primary) face a higher burden, compared to mothers with higher education levels (high school and above).
- Binary logistic regression showed individuals aged 6-15 years have a 1.6 times higher risk compared to those aged 16-25 years in the QOL domain Impact of symptoms. Additionally, in the QOL domain of health perception, individuals from nuclear families are having 2.8 times more risk compared to those from joint & three-generation families. In the caregiver’s burden analysis, Mothers with lower education (Illiterate & Primary school) are having 5 times more risk compared to the higher education (high school& above) and its findings were statistically significant in the binary logistic regression.
- In our study, recommendations were mainly establishment of T1DM registry at district level & Improvement of Healthcare Infrastructure in rural areas with regular stocking and supply of insulin at primary health care centers.

CONCLUSION

- Our study on Type 1 Diabetes Mellitus (T1DM) among children and adolescents, along with their caregivers, has provided significant insights into the multifaceted challenges they face. This research highlights the complex interplay of sociodemographic factors, clinical management challenges, caregiver burden, Quality of life & patient well-being in the context of T1DM.
- Quality of life of patients with T1DM are affected negatively by nuclear family type, lower socio-economic status, residing in rural areas and longer duration of diabetes. The study also highlighted the clinical management challenges faced by T1DM patients due to poor adherence to treatment with more than half of participants showing poor control HbA1c (>7.5).
- According to the WHO Well-Being Index, more than half of the patients with T1DM reported poor well-being. Longer diabetes duration showed negative impact on well-being of the patient.
- The majority of caregivers lacked knowledge about the treatment duration for T1DM, and a significant number were not adhering to dietary precautions for the patients. Caregivers, predominantly mothers who had younger age T1DM children and less educated were experienced more burden (moderate and severe).

RECOMMENDATIONS:

❖ For T1DM Patients:

- **Quality of Life Assessment and Research**:

  Large population-based studies on the quality of life and well-being among T1DM patients using standardized scales, will help in filling the knowledge gap in Indian context broadly and more in underserved populations.

- **Psychosocial Support Services for Patients**:

  Introducing specialized psychosocial support services tailored to the unique needs of children and adolescents with T1DM will help in addressing emotional well-being, peer support networks will facilitate to cope with the psychosocial impact of living with a chronic illness.

- **Integration of T1DM Education in Schools**:

  Incorporate comprehensive diabetes awareness and management education into school curriculum. Educate teachers and school staff on diabetes management protocols to create a supportive environment for students with T1DM and promote early recognition of symptoms and reduce stigma.

- **Regular Monitoring and Early Intervention Protocols**:

  Implement and enforce regular health screenings and monitoring protocols for T1DM patients to detect complications early. Include routine checks for HbA1c levels, comprehensive annual eye exams, and renal function assessments. Early detection allows for timely interventions, reducing the risk of long-term complications.

❖ For Care givers of T1DM Patients

- **Enhanced Educational Programs for Caregivers**:

  Develop and implement comprehensive educational programs tailored for caregivers, focusing on diabetes management strategies such as dietary control, blood sugar monitoring, and insulin therapy. Ensure these programs are accessible and suitable for caregivers with varying literacy and educational backgrounds.

  Additionally, establish and promote support groups or counseling services for caregivers of children and adolescents with Type 1 Diabetes Mellitus (T1DM) to provide psychological support, coping strategies for managing caregiver burden.

❖ Policy related recommendations

- **Regular stocking and supply of Insulin**:

  Strengthen healthcare infrastructure in rural areas to ensure equitable access to diabetes care and maintain regular stocking and supply of Insulin at primary health care centers. Expand outreach programs and telemedicine services to reach remote populations effectively. Foster collaboration with private practitioners and community health workers to enhance continuity of care and support for T1DM patients.

- **Establishment of T1DM Registry**:

  Initiate efforts to establish a T1DM registry at the district level. Collaborate with district health officers and healthcare providers to compile comprehensive data on T1DM prevalence, management practices, and patient outcomes. Encouraging the private practitioners to maintain the registry and notify with incentives will increase the data availability and help in future studies.

  Engaging Type 1 Diabetes (T1DM) patients and their caregivers in policy changes.

  Involving Type 1 Diabetes (T1DM) patients and their caregivers in policy changes ensures that their unique needs and perspectives are considered, leading to more effective and tailored healthcare policies. This collaborative approach can improve the overall management and support systems for T1DM patients.

Strengths of the study:

- **Addressing the Gap in Indian Literature on T1DM:** This study fills a significant research void in India context and more specifically in underserved areas like North Karnataka, by providing insights into the Quality of Life (QoL), well-being, and caregiver burden associated with T1DM, and lays the groundwork for future research and provides valuable insights for healthcare providers and policy makers.
- **Utilization of Comprehensive Assessment Tools:** The study used validated scales to assess Quality of life (QOL) and caregiver burden, offering a detailed understanding of T1DM's impact on their life and help in framing intervention.
- **Evaluation of Knowledge, Attitudes, and Practices (KAP) of Caregivers:** The study assessed caregivers' KAP regarding T1DM care, identifying knowledge gaps and support needs, providing essential information for creating educational programs and support systems to improve patient outcomes and reduce caregiver stress.

- **This study was funded by ICMR under PG-Thesis Grant 2022 & Intra mural funding from BLDE University.**

Limitations of the study:

- **Generalizability:**

  This study was focused on sample of Type 1 Diabetes Mellitus (T1DM) patients attending the 3 major hospital settings in Vijayapura city of North Karnataka. As a result, the sample may not fully represent all T1DM patients in the district, limiting the generalizability of the findings.

- **Self-Reported and Recall Bias**: The study utilized structured interviews and questionnaires, which rely on participants' recall and willingness to report accurately. This could lead to overestimation or underestimation of certain factors such as symptoms experienced, quality of life impacts or caregiver burden.

- **Duration of Study:** The cross-sectional design limits the ability to establish causality or observe changes over time. Longitudinal studies would provide more insight into the evolving challenges and impacts of T1DM on patients and caregivers.

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ANNEXURE-1

QUESTIONNAIRE

Study to assess factors influencing health-related Quality of life in people with Type-1 Diabetes mellitus and their Caregiver Burden in Vijayapura district

Socio-demographic questionnaire (To be answered by the caregiver of T1DM patient)
Date of interview: Patient ID:

Name	
Age	
Gender	Male --1 Female ---------------------------2 Others ----------------------------3
Education	Never attended--------------------------------- 0 Pre/Primary School -------------------1 High School ------------------------2 PUC/Diploma- ----------------------3 Degree and above --------------------4
Residence	Urban---1 Rural---2
Religion	Hindu -- ----1 Muslim ----------------------------2 Christian --------------------------3 Jain/Buddhist ----------------------4 Others ----------------------------5

Caste	SC---1 ST ------------------------------- 2 OBC ------ -------------------------------------3 General -- 4 Others (specify ________________) -------- 5 Refused--------------------------------- 999
Father's literacy	Never attended---------------------------------- 0 Pre/Primary School -------------------1 High School ------------------------2 PUC/Diploma ----------------------3 Degree and above --------------------4
Father's occupation	Daily wages------------------------------------ 1 Agriculture --2 Services ----------------------------3 Business --------------------------4 Others -----------------------------5
Mother's literacy	Never attended--------------------------------- 0 Pre/Primary School -------------------1 High School ------------------------2 PUC/Diploma ----------------------3 Degree and above -------------------4
Mother's occupation	Homemaker------------------------------------ 1 Daily wage ------------------------2 Agriculture ------------------------3 Services ---------------------------4 Business --------------------------5 Others -----------------------------6
Primary Care Giver	Mother-----------------------------------1
	Other relatives--------------------------2

Type of family	Nuclear -- 1 Joint ------------------------------ 2 Three generation ------------------------------- 3
Average monthly income of the family	>8220 -- 1 4110-8219 ------------------------2 2465-4109 ------------------------3 1230-2464 ------------------------4 <1230 ----------------------------5

Clinical characteristics

Symptoms (if sugar levels not in control)	Frequent urination------------------------1
	Giddiness----------------------------------2
	Abdominal pain---------------------------3
	Blurring of vision-------------------------4
	Others--------------------------------------5
Sleep Pattern	Normal-------------------------------------1
	Disturbed----------------------------------2
Bowel and Bladder habits	Regular-------------------------------------1
	Irregular------------------------------------2

Duration & Treatment Characteristics

Diabetes Duration	Less than 1 year---------------------------------1
	More than 1 year--------------------------------2
Frequency of insulin administration	Twice daily--------------------------------------1
	Three times per day-----------------------------2
HbA1c levels	Good control (<7.5%) --------------------------1
	Poor control (>7.5%) ---------------------------2

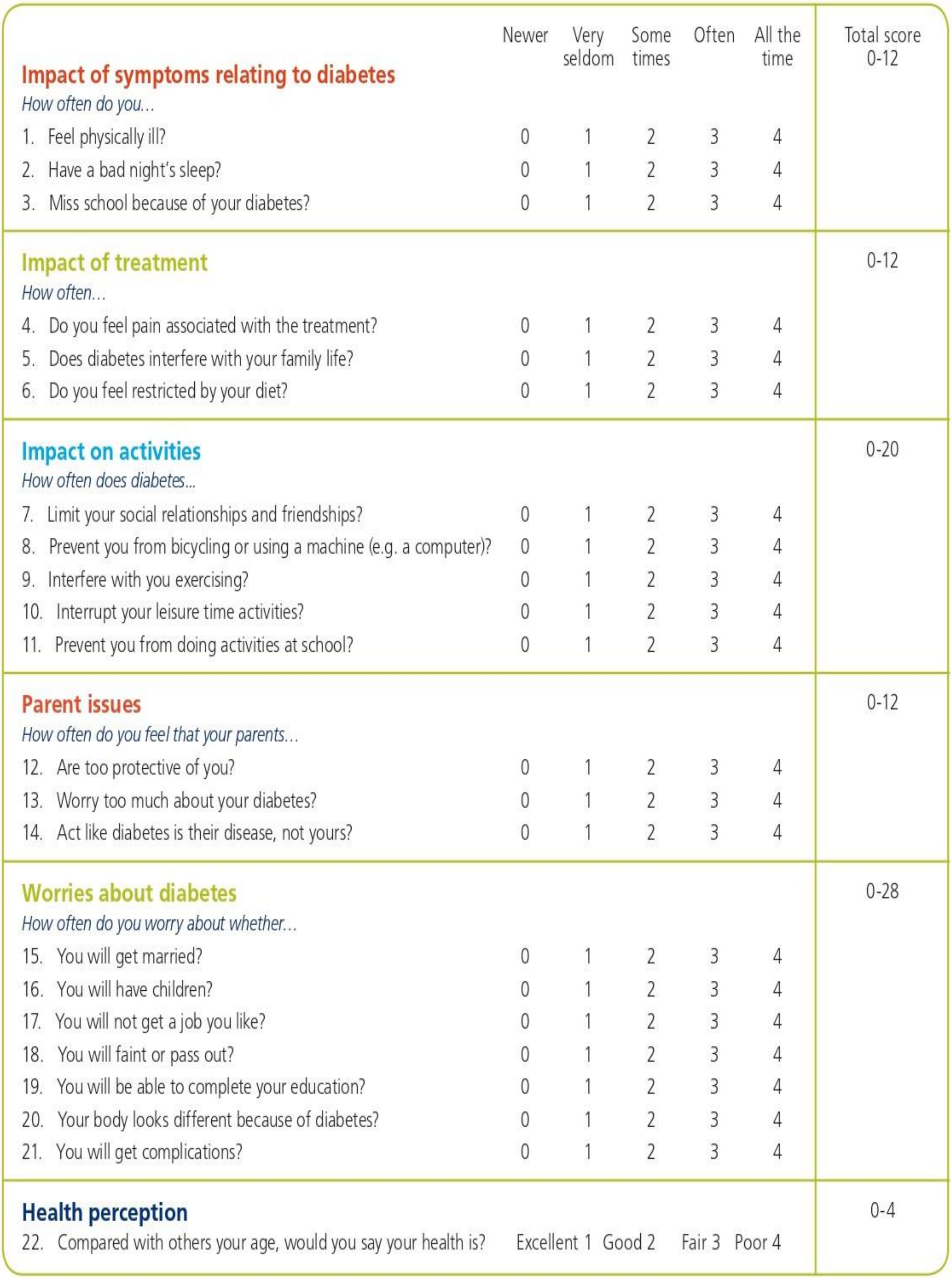
Knowledge, Attitude & Practice of Caregivers About T1DM

Do you know what is T1DM?	Aware--1
	Not aware-----------------------------------0
Do you know how long the treatment for T1DM Will take?	Aware--1
	Not aware-----------------------------------0
Do you know what is the treatment for this condition?	Aware--1
	Not aware-----------------------------------0
Do you Know the dietary precautions for a T1DM Patient?	Aware--1
	Not aware-----------------------------------0
Do you Know the Normal range of blood sugar levels	Aware--1
	Not aware-----------------------------------0

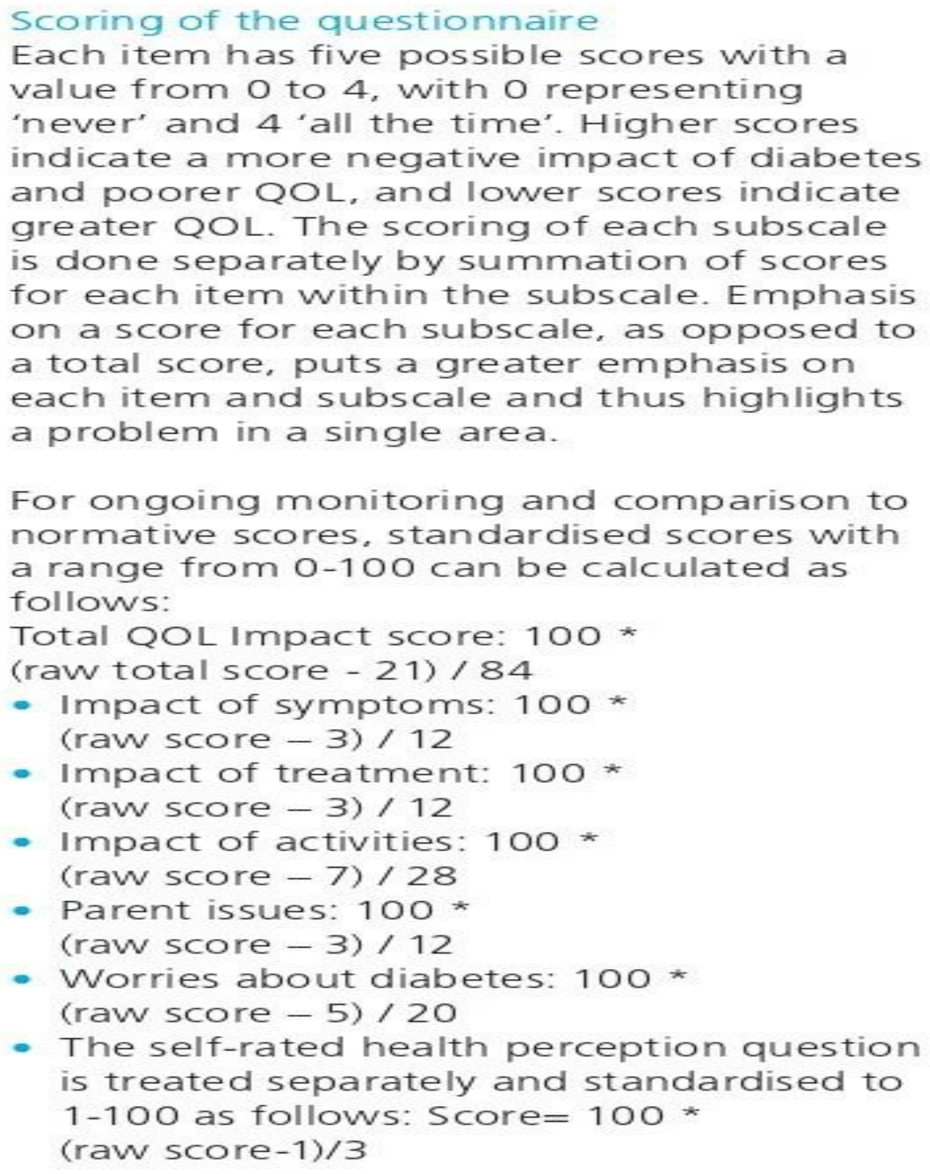
Should a patient with T1DM follow a controlled and planned diet?	Yes-----------------------------------1
	No-----------------------------------0
Do you think regular monitoring of blood sugar levels is necessary?	Yes-----------------------------------1
	No-----------------------------------0
Should a patient with T1DM Visit their physician regularly?	Yes-----------------------------------1
	No-----------------------------------0
Do you think regular insulin treatment is vital for managing T1DM?	Yes-----------------------------------1
	No-----------------------------------0
Should we Exercise Regularly to keep sugar levels under control?	Yes-----------------------------------1
	No-----------------------------------0

When was your blood sugar level last measured?	With in 1week-------------------------------------1
	More than 1 week---------------------------------2
When was your last consultation with a physician?	With in 1 month-----------------------------------1
	More than 1 month-------------------------------2
How often do your children engage in physical activity?	Daily---1
	Weekly---2
	Rarely--3
Are your children following dietary measures?	Following---1
	Not following------------------------------------2
Are your children taking insulin regularly?	Regular---1
	Irregular--2
If irregular reasons	Having fear of needle----------------------------1
	Low income -------------------------------------2
	Fear of Hypoglycaemia--------------------------3
	Forgot to take-------------------------------------4

Questionnaire to assess Quality of Life in T1DM Patients



	Newer	Very seldom	Some times	Often	All the time	Total score
Impact of symptoms relating to diabetes						0-12
How often do you…						
1. Feel physically ill?	0	1	2	3	4	
2. Have a bad night's sleep?	0	1	2	3	4	
3. Miss school because of your diabetes?	0	1	2	3	4	
Impact of treatment						0-12
How often…						
4. Do you feel pain associated with the treatment?	0	1	2	3	4	
5. Does diabetes interfere with your family life?	0	1	2	3	4	
6. Do you feel restricted by your diet?	0	1	2	3	4	
Impact on activities						0-20
How often does diabetes...						
7. Limit your social relationships and friendships?	0	1	2	3	4	
8. Prevent you from bicycling or using a machine (e.g. a computer)?	0	1	2	3	4	
9. Interfere with you exercising?	0	1	2	3	4	
10. Interrupt your leisure time activities?	0	1	2	3	4	
11. Prevent you from doing activities at school?	0	1	2	3	4	
Parent issues						0-12
How often do you feel that your parents…						
12. Are too protective of you?	0	1	2	3	4	
13. Worry too much about your diabetes?	0	1	2	3	4	
14. Act like diabetes is their disease, not yours?	0	1	2	3	4	
Worries about diabetes						0-28
How often do you worry about whether…						
15. You will get married?	0	1	2	3	4	
16. You will have children?	0	1	2	3	4	
17. You will not get a job you like?	0	1	2	3	4	
18. You will faint or pass out?	0	1	2	3	4	
19. You will be able to complete your education?	0	1	2	3	4	
20. Your body looks different because of diabetes?	0	1	2	3	4	
21. You will get complications?	0	1	2	3	4	
Health perception						0-4
22. Compared with others your age, would you say your health is?	Excellent 1	Good 2		Fair 3	Poor 4	



Scoring of the questionnaire

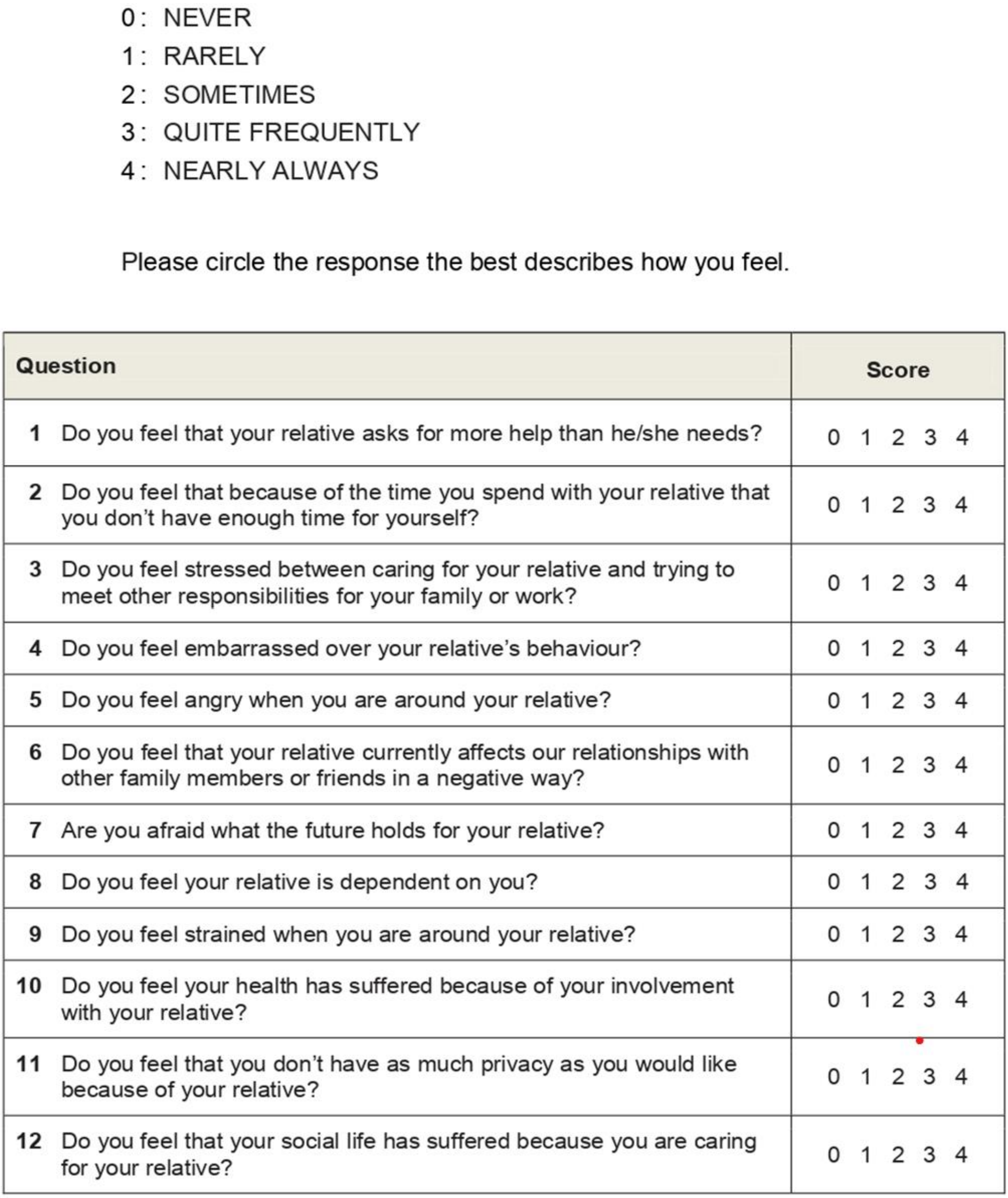
Each item has five possible scores with a value from 0 to 4, with 0 representing 'never' and 4 'all the time'. Higher scores indicate a more negative impact of diabetes and poorer QOL, and lower scores indicate greater QOL. The scoring of each subscale is done separately by summation of scores for each item within the subscale. Emphasis on a score for each subscale, as opposed to a total score, puts a greater emphasis on each item and subscale and thus highlights a problem in a single area.

For ongoing monitoring and comparison to normative scores, standardised scores with a range from 0-100 can be calculated as follows:

Total QOL Impact score: 100 * (raw total score - 21) / 84

- Impact of symptoms: 100 * (raw score – 3) / 12
- Impact of treatment: 100 * (raw score – 3) / 12
- Impact of activities: 100 * (raw score – 7) / 28
- Parent issues: 100 * (raw score – 3) / 12
- Worries about diabetes: 100 * (raw score – 5) / 20
- The self-rated health perception question is treated separately and standardised to 1-100 as follows: Score= 100 * (raw score-1)/3

Questionnaire to assess Caregivers burden (Zarit Burden Interview)



0 : NEVER
1 : RARELY
2 : SOMETIMES
3 : QUITE FREQUENTLY
4 : NEARLY ALWAYS

Please circle the response the best describes how you feel.

	Question	Score
1	Do you feel that your relative asks for more help than he/she needs?	0 1 2 3 4
2	Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0 1 2 3 4
3	Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0 1 2 3 4
4	Do you feel embarrassed over your relative's behaviour?	0 1 2 3 4
5	Do you feel angry when you are around your relative?	0 1 2 3 4
6	Do you feel that your relative currently affects our relationships with other family members or friends in a negative way?	0 1 2 3 4
7	Are you afraid what the future holds for your relative?	0 1 2 3 4
8	Do you feel your relative is dependent on you?	0 1 2 3 4
9	Do you feel strained when you are around your relative?	0 1 2 3 4
10	Do you feel your health has suffered because of your involvement with your relative?	0 1 2 3 4
11	Do you feel that you don't have as much privacy as you would like because of your relative?	0 1 2 3 4
12	Do you feel that your social life has suffered because you are caring for your relative?	0 1 2 3 4

Question	Score
13 Do you feel uncomfortable about having friends over because of your relative?	0 1 2 3 4
14 Do you feel that your relative seems to expect you to take care of him/her as if you were the only one he/she could depend on?	0 1 2 3 4
15 Do you feel that you don't have enough money to take care of your relative in addition to the rest of your expenses?	0 1 2 3 4
16 Do you feel that you will be unable to take care of your relative much longer?	0 1 2 3 4
17 Do you feel you have lost control of your life since your relative's illness?	0 1 2 3 4
18 Do you wish you could leave the care of your relative to someone else?	0 1 2 3 4
19 Do you feel uncertain about what to do about your relative?	0 1 2 3 4
20 Do you feel you should be doing more for your relative?	0 1 2 3 4
21 Do you feel you could do a better job in caring for your relative?	0 1 2 3 4
22 Overall, how burdened do you feel in caring for your relative?	0 1 2 3 4

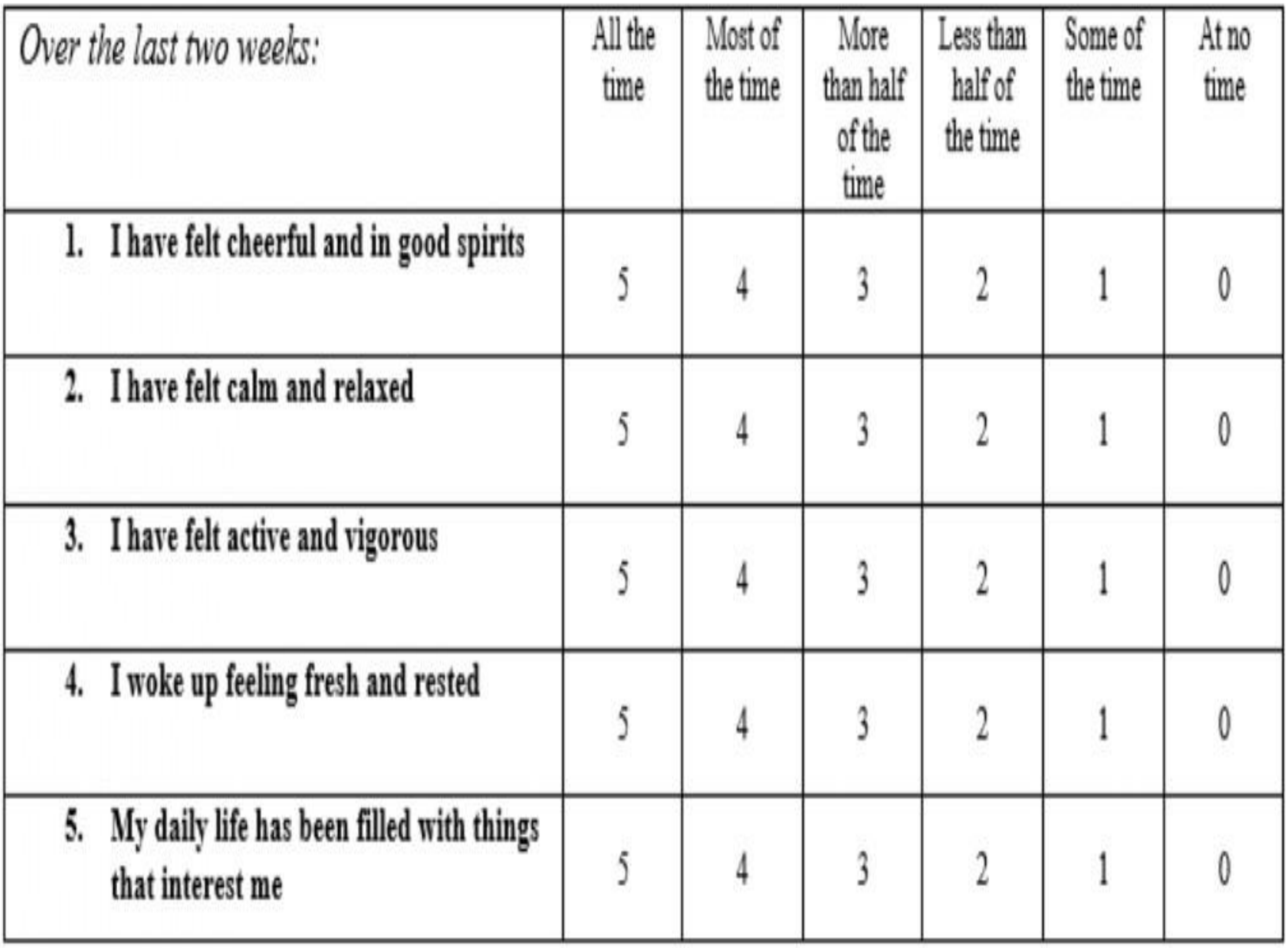
Interpretation: 0-20 No Burden

21-40 Mild Burden

41-60 Moderate Burden

61-88 Severe Burden

Questionnaire to assess well-being of T1DM Patients



Over the last two weeks:	All the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
1. I have felt cheerful and in good spirits	5	4	3	2	1	0
2. I have felt calm and relaxed	5	4	3	2	1	0
3. I have felt active and vigorous	5	4	3	2	1	0
4. I woke up feeling fresh and rested	5	4	3	2	1	0
5. My daily life has been filled with things that interest me	5	4	3	2	1	0

Interpretation: Score below 13 indicates Poor wellbeing.

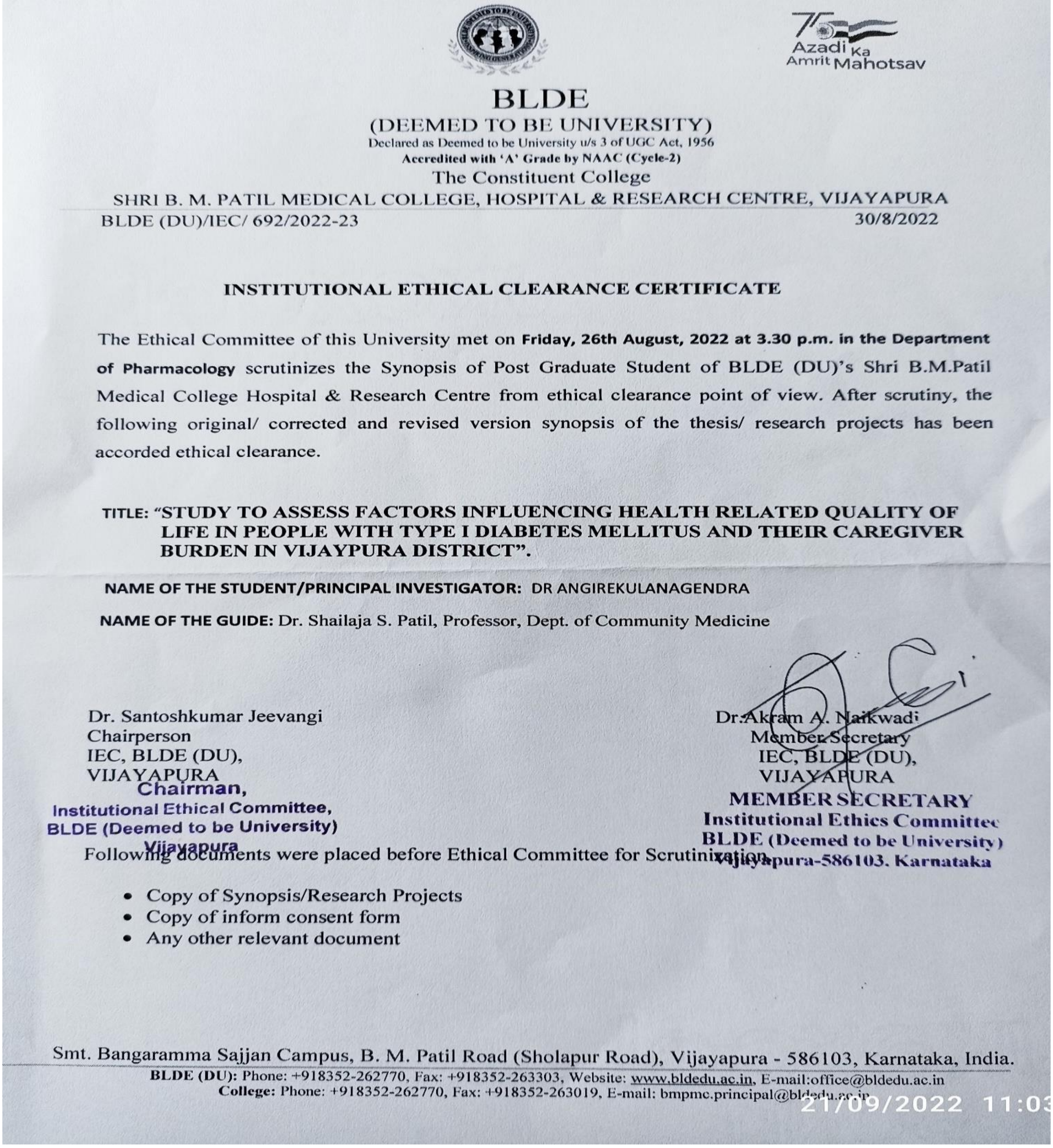
ANNEXURE-II
COPING STRATEGIES

ಟೈಪ್ 1 ಮಧುಮೇಹ ರೋಗಿಗಳ ಆರೈಕೆದಾರರಿಗೆ ನಿಭಾಯಿಸುವ ಸಲಹೆಗಳು

1. ಪರಿಸ್ಥಿತಿಯನ್ನು ಸ್ವೀಕರಿಸುವುದು
2. ದಿನಚರಿಯನ್ನು ಸ್ಥಾಪಿಸುವುದು
3. ಮುಂದಿನ ಯೋಜನೆ ಮಾಡುವುದು
4. ಸಾಮಾಜಿಕ ಬೆಂಬಲವನ್ನು ಪಡೆಯುವುದು
5. ಕುಟುಂಬ ಮತ್ತು ಸ್ನೇಹಿತರಿಂದ ಭಾವನಾತ್ಮಕ ಬೆಂಬಲವನ್ನು ಪಡೆಯುವುದು
6. ಆರೋಗ್ಯ ಪೂರೈಕೆದಾರರೊಂದಿಗೆ ಆರೋಗ್ಯಕರ ಸಂವಹನ ಮಾಡುವುದು
7. ತುರ್ತು ಪರಿಸ್ಥಿತಿಗೆ ಸಿದ್ಧತೆ ಮಾಡುವುದು
8. ಉಸ್ತುವಾರಿ ಮತ್ತು ದಾಖಲೆಯನ್ನು ಇಡುವುದು
9. ಸಂದರ್ಭಕ್ಕೆ ಅನುಗುಣವಾಗಿ ಹೊಂದಿಕೊಳ್ಳುವುದು
10. ಇನ್ಸುಲಿನ್ ಕೊರತೆಯ ಅಡೆತಡೆಗಳನ್ನು ನಿವಾರಿಸುವುದು

Dr. A NAGENDRA

ANNEXURE-III
ETHICAL CLEARANCE



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SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

Azadi Ka Amrit Mahotsav

BLDE (DU)/IEC/ 692/2022-23 30/8/2022

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this University met on **Friday, 26th August, 2022 at 3.30 p.m. in the Department of Pharmacology** scrutinizes the Synopsis of Post Graduate Student of BLDE (DU)'s Shri B.M.Patil Medical College Hospital & Research Centre from ethical clearance point of view. After scrutiny, the following original/ corrected and revised version synopsis of the thesis/ research projects has been accorded ethical clearance.

TITLE: "STUDY TO ASSESS FACTORS INFLUENCING HEALTH RELATED QUALITY OF LIFE IN PEOPLE WITH TYPE I DIABETES MELLITUS AND THEIR CAREGIVER BURDEN IN VIJAYPURA DISTRICT".

NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR: DR ANGIREKULANAGENDRA

NAME OF THE GUIDE: Dr. Shailaja S. Patil, Professor, Dept. of Community Medicine

Dr. Santoshkumar Jeevangi
Chairperson
IEC, BLDE (DU),
VIJAYAPURA

Chairman,
Institutional Ethical Committee,
BLDE (Deemed to be University)
Vijayapura

Dr.Akram A. Naikwadi
Member Secretary
IEC, BLDE (DU),
VIJAYAPURA

MEMBER SECRETARY
Institutional Ethics Committee
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

Following documents were placed before Ethical Committee for Scrutinization.

- Copy of Synopsis/Research Projects
- Copy of inform consent form
- Any other relevant document

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.
BLDE (DU): Phone: +918352-262770, Fax: +918352-263303, Website: www.bldedu.ac.in, E-mail:office@bldedu.ac.in
College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldedu.ac.in

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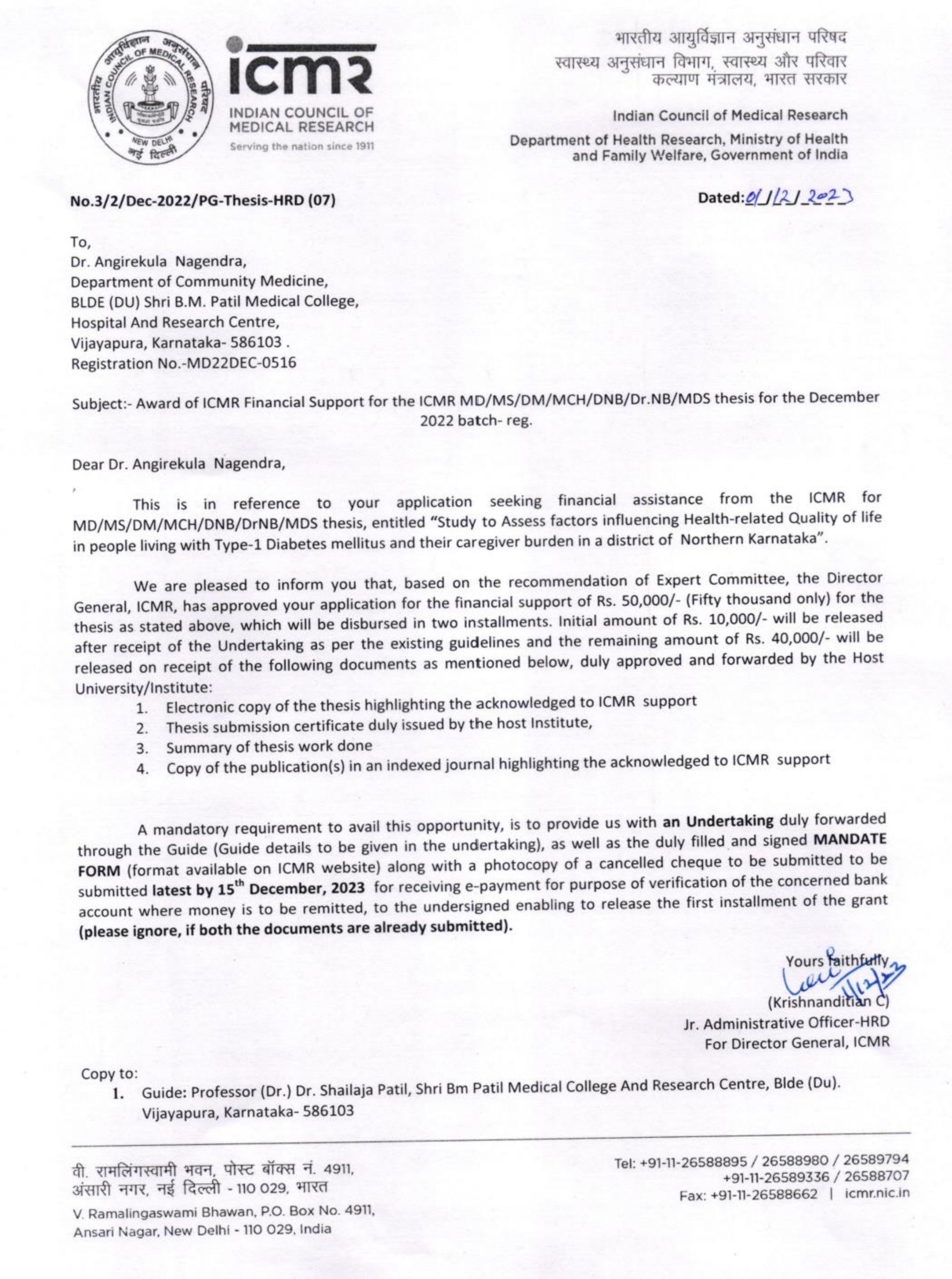
ANNEXURE-IV
ICMR-THESIS GRANT



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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

No.3/2/Dec-2022/PG-Thesis-HRD (07)

Dated: 01/12/2023

To,
Dr. Angirekula Nagendra,
Department of Community Medicine,
BLDE (DU) Shri B.M. Patil Medical College,
Hospital And Research Centre,
Vijayapura, Karnataka- 586103 .
Registration No.-MD22DEC-0516

Subject:- Award of ICMR Financial Support for the ICMR MD/MS/DM/MCH/DNB/Dr.NB/MDS thesis for the December 2022 batch- reg.

Dear Dr. Angirekula Nagendra,

This is in reference to your application seeking financial assistance from the ICMR for MD/MS/DM/MCH/DNB/DrNB/MDS thesis, entitled "Study to Assess factors influencing Health-related Quality of life in people living with Type-1 Diabetes mellitus and their caregiver burden in a district of Northern Karnataka".

We are pleased to inform you that, based on the recommendation of Expert Committee, the Director General, ICMR, has approved your application for the financial support of Rs. 50,000/- (Fifty thousand only) for the thesis as stated above, which will be disbursed in two installments. Initial amount of Rs. 10,000/- will be released after receipt of the Undertaking as per the existing guidelines and the remaining amount of Rs. 40,000/- will be released on receipt of the following documents as mentioned below, duly approved and forwarded by the Host University/Institute:

1. Electronic copy of the thesis highlighting the acknowledged to ICMR support
2. Thesis submission certificate duly issued by the host Institute,
3. Summary of thesis work done
4. Copy of the publication(s) in an indexed journal highlighting the acknowledged to ICMR support

A mandatory requirement to avail this opportunity, is to provide us with **an Undertaking** duly forwarded through the Guide (Guide details to be given in the undertaking), as well as the duly filled and signed **MANDATE FORM** (format available on ICMR website) along with a photocopy of a cancelled cheque to be submitted to be submitted **latest by 15th December, 2023** for receiving e-payment for purpose of verification of the concerned bank account where money is to be remitted, to the undersigned enabling to release the first installment of the grant **(please ignore, if both the documents are already submitted).**

Yours faithfully
1/12/23
(Krishnanditian C)
Jr. Administrative Officer-HRD
For Director General, ICMR

Copy to:
1. Guide: Professor (Dr.) Dr. Shailaja Patil, Shri Bm Patil Medical College And Research Centre, Blde (Du). Vijayapura, Karnataka- 586103

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं. 4911,
अंसारी नगर, नई दिल्ली - 110 029, भारत
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Ansari Nagar, New Delhi - 110 029, India

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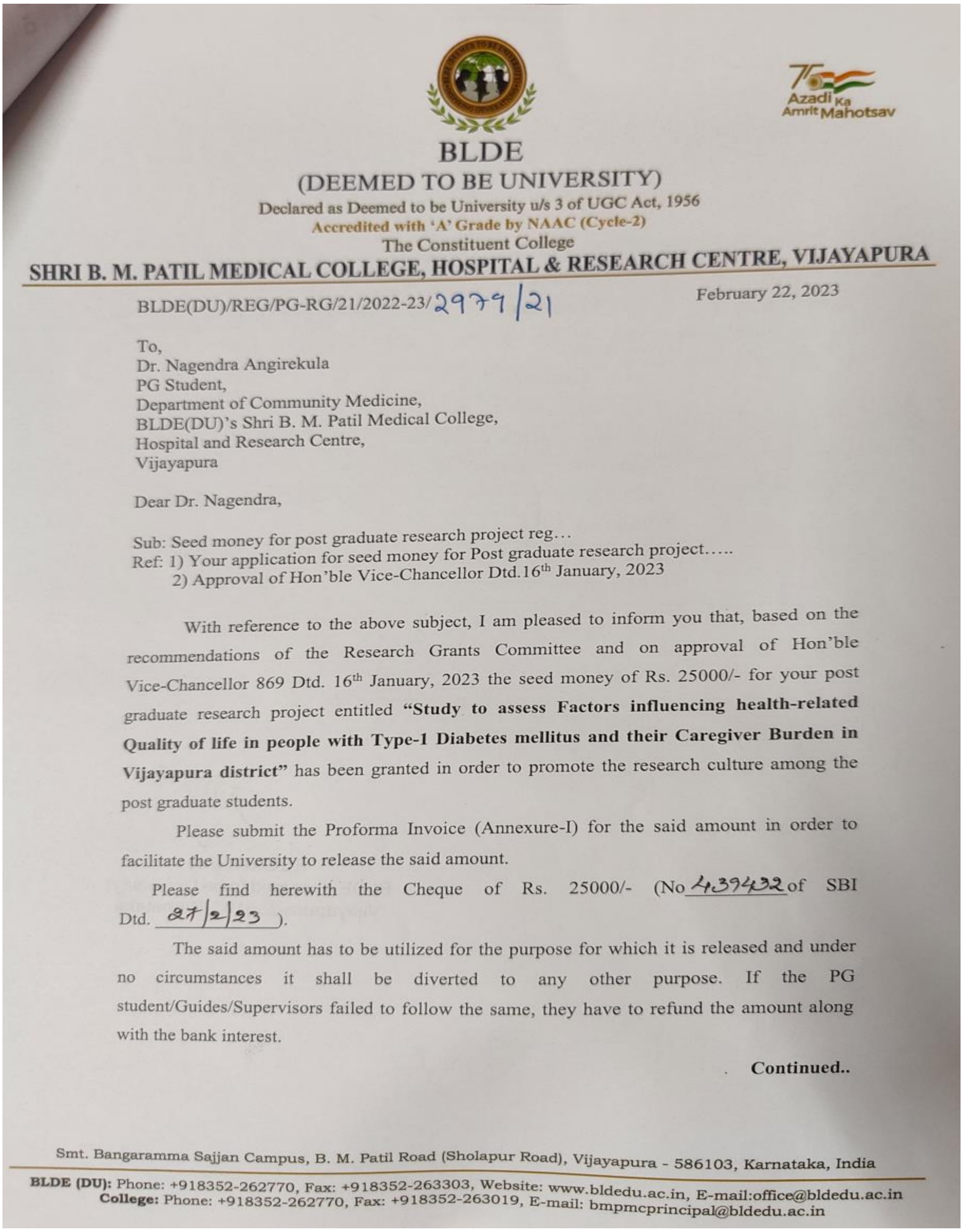
ANNEXURE-V

BLDE INTRAMURAL GRANT



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BLDE(DU)/REG/PG-RG/21/2022-23/2979/21

February 22, 2023

To,
Dr. Nagendra Angirekula
PG Student,
Department of Community Medicine,
BLDE(DU)'s Shri B. M. Patil Medical College,
Hospital and Research Centre,
Vijayapura

Dear Dr. Nagendra,

Sub: Seed money for post graduate research project reg…
Ref: 1) Your application for seed money for Post graduate research project…..
2) Approval of Hon'ble Vice-Chancellor Dtd.16th January, 2023

With reference to the above subject, I am pleased to inform you that, based on the recommendations of the Research Grants Committee and on approval of Hon'ble Vice-Chancellor 869 Dtd. 16th January, 2023 the seed money of Rs. 25000/- for your post graduate research project entitled **"Study to assess Factors influencing health-related Quality of life in people with Type-1 Diabetes mellitus and their Caregiver Burden in Vijayapura district"** has been granted in order to promote the research culture among the post graduate students.

Please submit the Proforma Invoice (Annexure-I) for the said amount in order to facilitate the University to release the said amount.

Please find herewith the Cheque of Rs. 25000/- (No 439432 of SBI Dtd. 27/2/23).

The said amount has to be utilized for the purpose for which it is released and under no circumstances it shall be diverted to any other purpose. If the PG student/Guides/Supervisors failed to follow the same, they have to refund the amount along with the bank interest.

Continued..

ANNEXURE-VI

PARTICIPANT INFORMATION SHEET

PURPOSE OF RESEARCH:

I have been informed that this study will help in improving overall health quality of life in type 1 D.M. patients and also management of coping strategies in caregivers.

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

PROCEDURE:

I understand that relevant history will be taken and I will undergo detailed clinical examination and will also be explained about the required investigations as per standard protocol.

RISKS AND DISCOMFORTS:

I understand that I/my ward may experience some pain and discomfort during the examination or during any intervention. This is mainly the result of my condition and the procedure of this study is not expected to exaggerate these feelings which are associated with the usual course of diagnosis and treatment.

ALTERNATIVES:

Even if you decline in participation, you will get the routine line of management.

BENEFITS:

I understand that I/my ward's participation in this study will help Analyze the factors affecting the Quality of life in Type1 DM patients.

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator’s research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time Dr. Angirekula Nagendra is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent form will be given to me to keep it and for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr. Angirekula Nagendra will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights. I have explained to ____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date:

(Guide) (Investigator)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. Angirekula Nagendra has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore, I agree to give my consent to participate as a subject in this research project.

______________________________ __________________

(Participant) Date

______________________________ __________________

(Witness to above signature) Date

ANNEXURE-VII

INFORMED CONSENT FORM OF T1DM CAREGIVERS

I confirm that Dr. Angirekula Nagendra has explained the research's purpose, the study procedure, and the possible discomfort and benefits that I may experience during the study. Dr. Angirekula Nagendra has explained all the above in detail in my own language and I have understood the same. Therefore, I agree to give consent for my participation as a subject in this research project.

Date:

____

(Name of Study Participant)

____

(Signature of Study Participant)

CONSENT STATEMENT FROM PARENTS:

I confirm that Dr. Angirekula Nagendra has explained the research's purpose, the study procedure that my son/daughter will undergo & the possible discomfort and benefits that he/she may experience in my own language. I have been explained all the above in detail in my language and understand the same. Therefore, I agree to give consent for my ward's participation as a subject in this research project.

____

(Signature of the Parent / Guardian) Date:

____

(Signature of witness)

ASSENT FORM

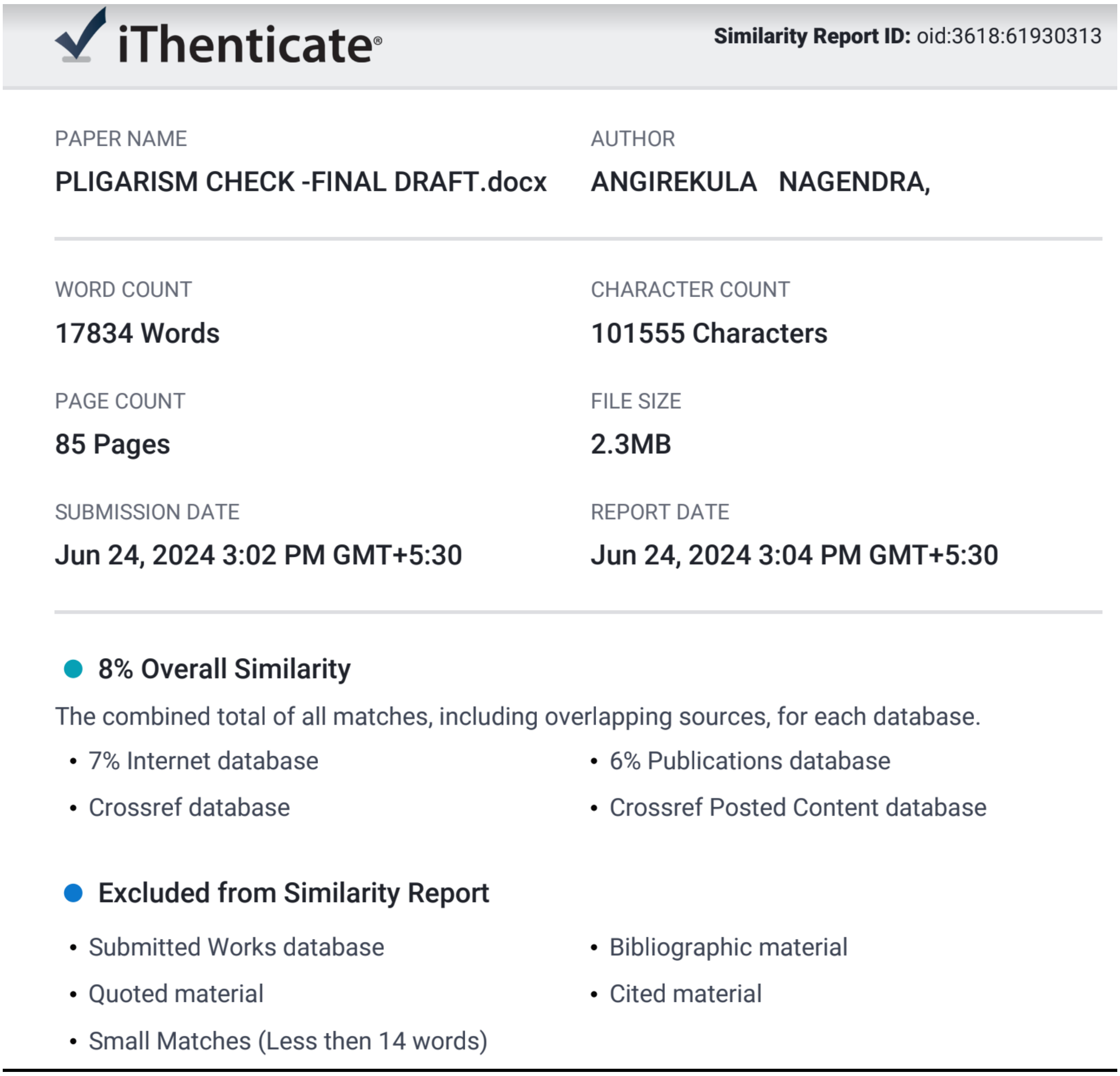
I have been asked to participate in a study on the topic "Study to assess Factors influencing health-related Quality of life in people with Type-1 Diabetes mellitus and their Caregiver Burden in Vijayapura district" done by Dr. Angirekula Nagendra under the guidance of Dr. Shailaja S Patil. By participating in this research, I will be asked a series of questions by the researcher regarding the topic. I have understood that the information about me will be kept secret, and I have the right to ask questions about my information and the result of the study. I have been informed that I will be able to leave the research at any time I want without any prejudice. I agree to be a part of this research.

Participants full Name:

Date:

ANNEXURE-VIII

PLAGIARISM REPORT



Similarity Report ID: oid:3618:61930313

PAPER NAME
PLIGARISM CHECK -FINAL DRAFT.docx

AUTHOR
ANGIREKULA NAGENDRA,

WORD COUNT
17834 Words

CHARACTER COUNT
101555 Characters

PAGE COUNT
85 Pages

FILE SIZE
2.3MB

SUBMISSION DATE
Jun 24, 2024 3:02 PM GMT+5:30

REPORT DATE
Jun 24, 2024 3:04 PM GMT+5:30

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ANNEXURE-IX

Gantt Chart

In Years	**2022**							**2023**												**2024**					
Activity	Jun	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Topic selection	■	■																							
Synopsis preparation and submission			■	■																					
Review of literature					■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Preparation of Proforma							■	■	■	■															
Data collection											■	■	■	■	■	■	■	■	■	■	■				
Data analysis																						■	■	■	
Dissertation writing																				■	■	■	■	■	■
Dissertation submission																									■

ANNEXURE-X

PHOTOGRAPHS

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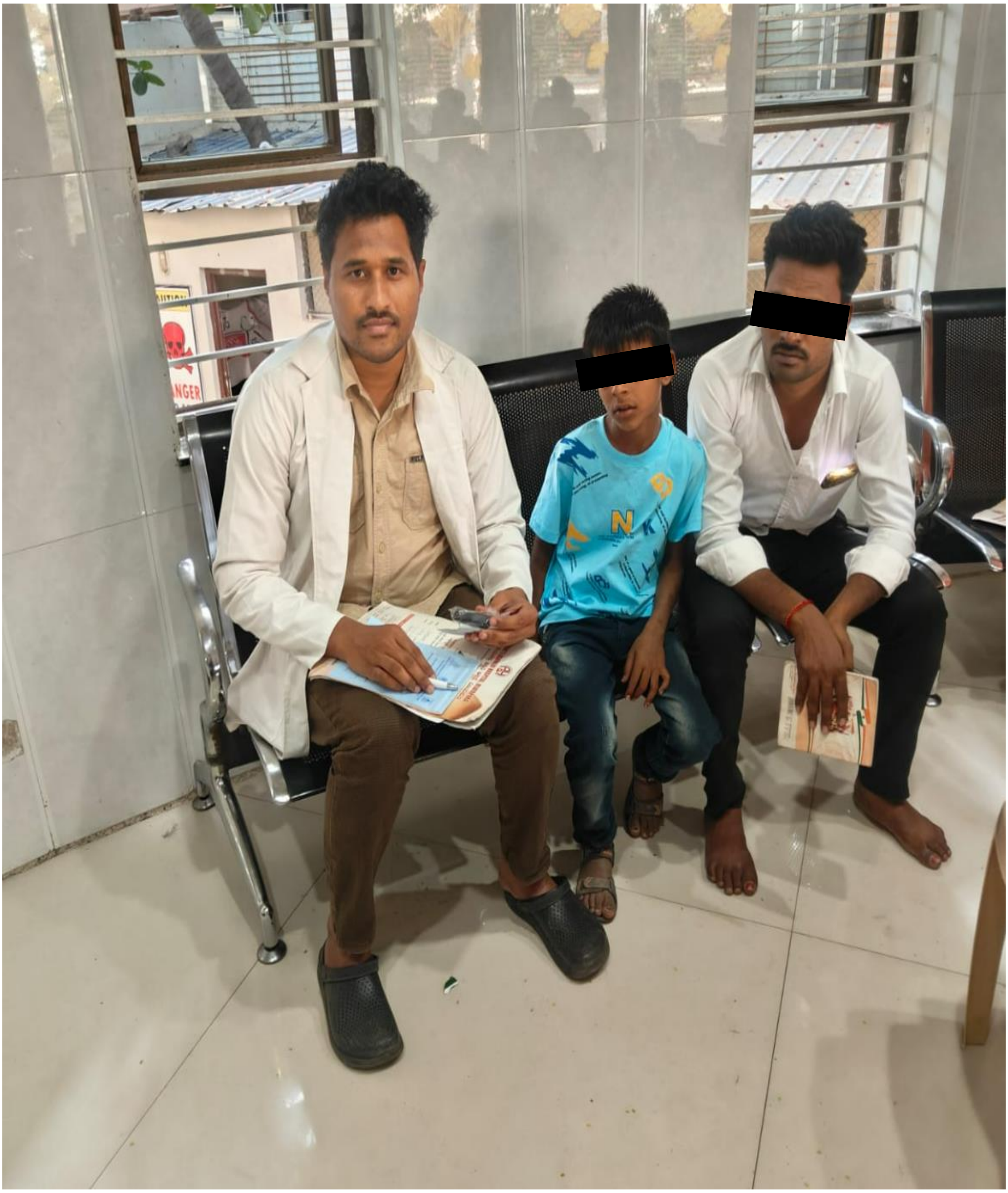

[redacted]

[redacted]


JAI JAWAN
FOCUS