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Characterizing Common Challenges Faced by Parental Caregivers of Children with Type 1 Diabetes Mellitus in Mainland China: A qualitative study

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Abstract

Objectives: Parental caregiver psychology affects outcomes of children with Type 1 Diabetes Mellitus (T1DM). This study aimed to qualitatively examine perceptions of common challenges among parental caregivers of children with T1DM (T1DM Parental Caregivers).

Setting: 45-60 minutes semi-structured interviews were conducted with T1DM Parental Caregivers. Interview recordings were transcribed and coded in NVivo 11.0 to observe emergent themes.

Participants: Eligible T1DM Caregiving Parents (parent(s) and/or legal guardian(s)) were identified from caregivers attending visits with children hospitalized or assessed in the Pediatric Neuroendocrinology Department of Shengjing Hospital, China Medical University in Shenyang from January 2018 to June 2019.

Primary and secondary outcome measures: Not applicable.

Results: Content analysis revealed 5 common themes with 14 subthemes, including persistent psychological stress (catastrophic emotions, emotional distress, and altered self-efficacy), family function change (altered family life patterns and changes in parental role/function), challenges in daily management (technical challenges, emotional regulation, parent-child conflict, and transition of care autonomy from parent to child), financial burden (cost burden of treatment and altered family economics), and lack of social support (social activity limitations and insufficient support systems). All were highly saturated across interview data.

Conclusions: Young children with T1DM rely on parental caregivers for disease management and to one day become capable of autonomous self-management as they age. However, both the period of emotional disturbance during initial diagnosis, psychological stresses of long-term caregiving, and conflict emerging from transition

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for parental to child responsibility for care can cause psychological effects detrimental to parental caregivers and T1DM children. This work provides compelling evidence for the role of assessment and intervention in parental caregiver psychological and emotional wellbeing in diabetes care, as well as the need for improved social and school support for children with T1DM in China.

Keywords: Type 1 Diabetes Mellitus, Grounded Theory, Qualitative Methods, Caregiving, Diabetes Care, Psychological Perceptions

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Strengths and limitations of this study

1. This is the first study, which described the real condition of young children with T1DM rely on parental caregivers for disease management in China.

2. This study demonstrate that both the period of emotional disturbance during initial diagnosis, psychological stresses of long-term caregiving, and conflict emerging from transition for parental to child responsibility for care can cause psychological effects detrimental to parental caregivers and T1DM children.

3. This study provides compelling evidence for the role of assessment and intervention in parental caregiver psychological and emotional wellbeing in diabetes care.

4. This study is limited by the interpretation of the reviewers and coders.

5. This is a single-center study, which limited the generalizability of the findings of this study and a further multicenter study was needed.

Background

Type 1 Diabetes Mellitus (T1DM) is a common chronic disease in children, in which the parental caregiver and child diagnosed with T1DM must take on management tasks associated with the disease, with financial, emotional, and social impact on the family unit[1]. An increasing number of families with young children are impacted by T1DM, with the incidence of T1DM increasing by as much as 2% to 5% each year worldwide[2]. In China, the incidence of T1DM in children is currently 5.6 per 100,000 live births[3]. Although the incidence of T1DM in China is lower than that in Europe or the United States, China ranks fourth among countries for T1DM occurrence—and the number of cases is increasing each year[4]. However, communities in China generally have less resources and fewer T1DM cases outside of urban centers, which can increase the strain on Chinese parental caregivers. Thus, examining the situation of middle- and low-income parents of children with T1DM in China is essential to improving resources for T1DM care and long-term outcomes.

Management of T1DM in children involves changes in daily living activities that affect not only the child receiving care but also the caregiver, including responsibility to ensure continuous glucose monitoring (4 or more times per day) and insulin injection using an insulin pump or injecting insulin multiple times a day, as well as tracking and calculating daily carbohydrate intake and physical activity levels important to prevention of hypoglycemic and hyperglycemic episodes[5,6]. Children with T1DM under age 13 are unable to self-manage their T1DM care, and instead rely heavily on their parental caregiver for disease management[7]. Treatment for children with T1DM is aimed at ensuring stable blood glucose levels, minimizing occurrence of potentially deadly hypoglycemic events, and preventing long-term complications of diabetes as the child grows[8]. These responsibilities place immense psychological financial stress on

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parental caregivers.

Owning to the relatively lower incidence of T1DM outside of urban centers in China, the emotional toll, financial burden, and social isolation experienced by parental caregivers of young children with T1DM can be immense. Despite improvements in T1DM medications and treatment technologies, many children in child still experience adverse health effects due to blood glucose control[9]. Recent research suggests that, more than 58.6% of children with T1DM in China do not achieve sustained hemoglobin control (glycosylated hemoglobin lower than 7.5%)[10]. This can lead to complications caused by poor blood glucose control that have adverse impact on the child's growth and long-term health, and place significant burden on caregivers and the family unit. Thus, there is a need to study T1DM care, and its impact on parental caregivers, through a social lens.

Rankin et al. (2018)[1] used qualitative methods to examine the strategies and motivations of children with T1DM and their caregivers, providing insights into how diabetes management can be improved. Researchers have also demonstrated that successful disease management of children with T1DM not only requires the children to manage their individual health, but also requires their cooperation with caregivers who share the responsibility for the child's medical management[11]. These burdens can, however, result in caregiving parents of children with T1DM feeling isolated and helpless when faced with the challenges of chronic disease management. Psychologically, parents man manifest a sense of self-doubt, guilt, or anxiety, and many experience traumatic initial confusion as they try to integrate these new responsibilities into their family's routine when their child is first diagnosed[12]. These feelings may be transient or persist, and may be exacerbated if a child experiences hypoglycemic events or other emergency situations that contributes to caregiver trauma and anxiety[13-15]. Understanding the

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experiences of parental caregivers of children with T1DM is of great significance in improving clinical and social interventions to help parents adapt to the role of caregiver, and achieve optimal health outcomes for their children. However, current research on children with T1DM in China is primarily limited to quantitative studies on the quality of life (QoL) of children[15], psychological state[16] and coping style of the children or their parents[17].

Qualitative research methodologies can provide actionable insights into the psychological state, behaviors, and motivations of patients and caregivers managing T1DM[1]. This socio-ethnographic study employees qualitative methods to examine the perceptions of parental caregivers of young children (aged 14 or younger) with T1DM in China, providing insights into the key challenges as caregivers transition from complete management of young children with T1DM to an older child with increasing autonomy over his or her medical care. Thus, this research is designed to provide actionable insights for improving social support and management of these patients, in a holistic context that considers the parental caregiver and family unit

Methods

Study Population and Design

Qualitative research methods were employed to examine social, emotional, and experiential perceptions of parent(s) and/or legal guardian(s) with children diagnosed with T1DM, referred to as T1DM Caregiving Parent for purposes of this article. Synchronous, in-person, semi-structured interviews were conducted to collect qualitative data, and emergent heuristic content analysis was subsequently performed on transcripts. Eligible T1DM Caregiving Parents were identified from caregivers attending visits with children hospitalized or assessed in the Pediatric Neuroendocrinology Department of Shengjing Hospital, China Medical University in

Shenyang from January 2018 to June 2019.

To be eligible for participation in study interview, T1DM Caregiving Parents were required to (1) be the parent and/or legal guardian of a child 14 years of age or younger with diagnosed T1DM, and (2) be a primary caregiver during at least 6 months of continuous care for child being treated for T1DM during this period[18] T1DM Caregiving Parents were considered ineligible to participate in interviews if (1) the child with T1DM also experienced other significant comorbidities or chronic diseases; (2) the child with T1DM was considered to required immediate medical care or treatment where the study could pose an undue burden on the patient or caregiver; (3) T1DM Caregiving Parent was unable to communication fluently in the local language of the investigator (Mandarin Chinese).

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board (IRB) of Shengjing Hospital, China Medical University, Shenyang, China (Approval no. 2018PS362K). All participants provided written informed consent prior to participating in interviews.

Sampling Methods and Process

Purposive nonprobability sampling was used, in which eligible T1DM Caregiving Parents were approached for participation as they presented in clinic. To ensure a representative sample, the heterogeneity of sample selection was expanded for T1DM Caregiving Parent age, marital status, education level, and T1DM child age and disease course. The study was discontinued when qualitative data reached saturation, which was expected to occur between 15 and 20 interviews, as previously described[19,20] When the number of interviews reached 20, the data in our research was saturated, and no new information was obtained, so sampling was terminated.

Data Collection

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An IRB-approved semi-structured interview outline was used to ensure consistency while performing interviews. The interview structure was based on the theory of individual and family self-management[21], and formulated through expert evaluation of the research purpose, population, and existent body of literature. The outline used in interviews is shown in **Table 1**. The planned duration of the interview was 45 to 60 minutes.

Upon arrival at the clinical site, the head nurse of the clinical unit familiar with the T1DM Caregiving Parent met the interviewee, led the interviewee to the interview site, and made introductions with the interviewer. Prior to the start of the interview, the interviewer explained the purpose, significance, methods, rights of the interviewee, and privacy protection measures. Written informed consent was then obtained before starting each interview.

The interview location was selected as audio visual classroom located in the Pediatric Neuroendocrinology Ward. This location was selected for the quiet environment, free of distractions. Interviews were conducted by the authors, who were provided with training on semi-structured interviews and use of neutral, objective, and non-leading language during the interview to maximize data integrity.

Data Transcription and Coding

Each interview was recorded using audio recording devices, and digitally transcribed asynchronously (with 48 hours after each interview) by the researchers. Transcripts were recorded in MS Word (Microsoft, USA), and verified by a second researcher. To ensure data integrity, interviewees were provided a copy of their interview transcript and allowed to suggest corrections, which, where appropriate, were assessed and integrated by the researchers upon review of the original recording.

Heuristic coding was performed using emergent grounded theory methods[20] manually

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using transcripts imported into NVivo 11.0 (QSR International, USA) using sort, manual code, summarize text data, and identify and refine themes. Coding was verified by a second researcher, the numbers were used to identify the interviewees in place of their real names, DM1-DM20. Emergent themes and subthemes were identified using a grounded theory approach.

Data Analysis and Reporting

Textual coding results in NVivo 11.0 (QSR International) were reported as counts and percentages (data not shown) and themes/sub-themes were presented descriptively using qualitative analysis methods. All analyses were performed in the local language of the interview conduct (Mandarin Chinese), and the data were analyzed and collected simultaneously. The theme of the interviews was extracted using content analysis methodology by way of three-grade coding. Final results were translated to English to broader access to these results. All translations were performed by the researchers to ensure integrity of translations.

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Results

Participant Characteristics

Saturation was reached when 20 T1DM Caregiving Parents (N = 20) completed interviews. Interviewed T1DM Caregiving Parents were aged 30 to 53 years of age (10.6±2.45), including 7 fathers and 13 mothers (gender roles were self-identified by the interviewee). Of these patients, 8 were caregivers of children with T1DM that were treated with islet pumps, and 12 were caregivers of children with T1DM that were treated with subcutaneous injections. Socio-demographic information for T1DM Caregiving Parents completing interviews and demographic and clinical condition of their children are summarized in **Table 2**.

By analyzing the transcripts of interviews, five emergent themes were observed consistently throughout the interview data: (1) persistent psychological stress; (2) family function changes; (3) challenges in daily management; (4) excessive economic burden; (5) lack of support system. Further, 14 subthemes within these 5 themes, summarized in **Table 3**. The themes/sub-themes are further characterized below.

Theme of Persistent Psychological Stress

Persistent psychological stress was identified as prominent theme across interviews, with four key sub-themes emerging from coding:

(1) Catastrophic Emotional Experience

In acute period following diagnosis, parents often experienced emotions that can be described as catastrophic, including shock, fearfulness, frustration, hopelessness, sadness, and feelings that disaster is imminent.

Interviewee DM2: "When the doctor told me that my child was diabetic, I felt like [I was] struck by lightning and the sky was falling. My child's life is basically over."

(2) Emotional Distress Based in Negative Emotions

Negative emotions observed in T1DM Caregiver Parents primarily included continual worry, anxiety, sadness, stigma, annoyance, and guilt. Worry was embodied in anxiety and sadness, often with connections to the uncertainty of disease progression in their child. Some parents also experienced symptoms of worry and invasive thoughts about the potential for their children to be discriminated against in the future because of their illness, leading some to even report hiding their child's illness in common social contexts. Further, parents reported feeling guilt linked to social isolation and dietary restrictions experienced by their child, etiology of illness (often linked to limited clinical understanding of T1DM), or feeling of being "at fault" for their child's condition.

Interviewee DM2: "It's still like a sword hanging over my head. I don't know when the

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complications will come. I live with fear every day."

Interviewee DM6: I don’t want people around to know that my child has diabetes. Diabetes is an undead cancer. Thinking about it in another way, who wants his child to marry a diabetic in the future? You may only have to marry someone who also has diabetes. My child doesn’t want her classmates to know that she is different from others."

Interviewee DM3: "My thoughts are that he is too young and suffers too much. He has to get injections and blood tests every day, and his fingers are pierced constantly. As a parent, I feel like a failure. I have not taken good care of my child and have been busy with work. I feel like I neglect taking care of him."

(3) Altered Sense of Self-Efficacy

T1DM Caregiver Parents also showed self-doubt owing to lack of experience in chronic disease care. In the most extreme cases, these feelings manifest as a severe lack of self-compassion, wherein parents expressed doubt in their ability to competently care for their child.

Interviewee DM6: "Taking care of [my daughter], it’s not that I think I can or can’t, but that I must be able to. It’s like a parent’s obligation. If I can’t, what else can she do? It’s not something I can or can’t do. It’s something I must be able to."

(4) Perceived Increased Responsibility for Parenting

T1DM Caregiver Parents reported perceiving a heavier burden of responsibility to manage their child’s disease and remain hypervigilant, in particular for young children with T1DM not capable of self-managing. Parents perceive that, compared to children without T1DM, both parents and children bore additional responsibilities.

Interviewee DM19: "Now our child is too young to take care of herself. As parents, we are duty-bound, we have to be good supervisors. We supervise our child's diet, exercise,

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blood glucose testing and injections. Although we are not professionals, we will be dedicated to protecting our child's health. "

Altered Facility Function

Changes in family life included two prominent subthemes:

(1) Changes in Patterns of Family Life

Changes in routine patterns of daily living within the family unit were consistently reported by T1DM Caregiver Parents. These changes included changes in family activities designed to assist children in adapting to their life after T1DM diagnosis. On one hand, parents reported striving to retain normalcy for their children; however, the child's T1DM was also often reported to be disruptive to others, particularly other children, in the family unit. Parents also reported aiming to incorporate blood glucose measurement in routine daily living activities of the family unit, with mixed success.

Interviewee DM16: "It is inevitable that [when living with a child with T1DM] you can't be the same as other families. We have to consider our child's physical strength and whether [he] can eat regularly. Especially when faced with a table of good food, it is uncomfortable for the child to see others eating.

Interviewee DM18: "Now we guide our child to think that measuring blood glucose and injecting insulin is a routine in life, just like showers before bed. We don't want our child to feel that injecting insulin before meals is a burden."

(2) Changes in Parental Role and Function

T1DM Caregiver Parents consistently reported that they perceived differences between their "normal" role and function compared with their prior lifestyle before their child's diagnosis. Specifically, T1DM Caregiver Parents expressed that their child's diagnosis affected their future career planning, life focus, and goals, and often resulting in a greater amount of time spent tending medical needs of their child.

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Interviewee DM5: "Now I rarely focus my energy on the company [I work for], just get off work as soon as possible. I used to leave early and return late to make money. Now I quit my job and found a new one that can make a living while taking care of my child. When she is on vacation, so am I."

In some cases significant housing and job/school changes are made to accommodate the child's T1DM care.

Interviewee DM14: "My family is in the countryside, but our child comes to a school in the city. Since our child has the disease, diabetes, and cannot live in school, I have to accompany him to study. My child and I rented a house near the school, which is convenient for me to take care of him, and we will return to the countryside during vacation, where his father works.

Challenges in Daily Management Theme

Challenges in daily management were consistency reported by T1DM Caregiver Parents, including:

(1) Technical Difficulties in Blood Glucose Management

T1DM Caregiver Parents reported technical difficulties in blood glucose management, including unsatisfactory or irregular blood glucose levels, primarily associated with dietary control, exercise compliance, untimely blood glucose monitoring, and insulin injection dosage adjustment. Parents expressed that lack of self-management, often owning to social and educational obligations, was often a key concern.

Interviewee DM3: "He is in the second grade of junior high school. There is a lot of tutoring outside school. He has to get up at 5:30 in the morning to study and finish school at 5:30 in the evening. If goes to the tutoring class, he returns at 8:30. There is no time to exercise. At school, his blood glucose control was poor [but] it is impossible to ask him to leave school to take measurements before and after meals."

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(2) Emotional Regulation

In addition to the regulation of T1DM Caregiver Parents' own emotions, interviewees also reported difficulty in assessing and managing their child's emotional and psychological needs.Interviewee DM14: "[My daughter with T1DM] feels that if her classmates know she is sick and can't be cured, she will be inferior to others. Often it was lunch at noon, and she went to the toilet to get an injection, because she is afraid of being discriminated against by her classmates or something. Our child's self-esteem is strong, so she ran the toilet for injections; at that time, if another child went to the toilet, she would be frightened, remove the needle and hurriedly put it away. She would not press and was still bleeding. As a parent, I feel distressed, but I don't know how to help the child's feel better

(3) Managing Parent-Child Conflict

Interviewees consistently reported that parent-child conflict stemmed from inability to communicate effectively and perception of their children's poor compliance with disease management. As children age and their sense of autonomy increases, parents reported difficulty in transitioning to stages where their child exerts greater autonomy over their T1DM care and monitoring. In particular, interviewees reported resistance from their child, and perceptions that the child felt controlled by the parent's actions. Interviewee DM20: "I understand that the child is also upset and there is no place to vent. I restrict her eating and control her blood glucose measurements. How can she not resist psychologically? I feel that I can't get into her heart, I don't know how to get along with her."

(4) Transition from Parental Management to Self-Management as the Child Ages

With changes in their child's growth and developmental stage, the roles and function of children and parents in T1DM management shifts. However, premature transfer of

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diabetes management tasks to children with T1DM is now considered a factor leading to poor blood glucose control. Many T1DM Caregiver Parents expressed uncertainty or frustration on transition timing.

Interviewee DM15: "In the first year, we helped her with her insulin injections, and then she did it by herself for the next two years. The blood glucose monitoring at night was not done, so the glucose control was not good. Such an old child is really difficult to manage, half-sensible but not sensible."

Excessive Financial Burden Theme

T1DM Caregiver Parents consistently reported the excessive financial burden of caring for a child with T1DM, including high cost of treatment. This burden was often cited as a factor for job and educational changes, affecting family member circumstances. Due to the long-term nature of treatment, medications and injection supplies are consumable items with sustained cost impact. Further, caring for a young child with T1DM often requires care around the clock, with some parents reporting that one of parent gave up employment, changed employment, or reduced hours to provide adequate care for their child, often decreasing household income and adding further financial stress to middle- and low-income families.

Interviewee DM2: "Using an insulin pump is a great economic pressure. It costs nearly 20,000 CNY a year. A tube is normally more than 110 CNY. I will buy some during sales and let my friends buy some more from other channels. A tube can be used for three days. It costs nearly 20,000 CNY a year."

Lack of Social Support Systems Theme

The lack of support system primarily includes limited social activities and insufficient social support system, as described below:

(1) Lack of Limited Social Activities

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At present, the family structure in China is dominated by a typical nuclear family, and children are generally a primary focus of the family unit. Once a child is diagnosed with T1DM, T1DM Caregiver Parents reported feeling disruption in the social activities of the family unit. In particular, mothers in the interview often left their employment, changed careers, or reduced hours to allow for caregiving for their child with T1DM. This transition can result in social isolation and limit normal social activities of the parent.

Interviewee DM10: "Since my child had a ketosis coma, I have never dared to relax again. I have lost myself. Every day in the year, there are no more visits to relatives or friends."

(2) Insufficient Other Support Systems

Insufficient other systems of social support was a common concern of T1DM Caregiver Parents, especially those of children reaching school age and assuming autonomy over their care during school hours.

Interviewee DM12: "Unlike other countries, our children do not have diabetes nurses in school. When the child is at school, every time the teacher calls, I am terrified, always scared that something bad will happen. If the child's blood glucose is low, does the teacher know how to handle it? Will it be delayed?"

Discussion

This study employed qualitative research methods via semi-structured interviews with parental caregivers of children with T1DM. Using Grounded Theory (GT), a method based in social science research, [20-21] the researchers examined and consolidated emergent themes from interview transcripts. GT methods are designed to allow emergence of previously undetected patterns or trends in social communications. In this study, parental caregivers of T1DM children consistently reported Persistent

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psychological stress, changes in routine functions of the family unit, challenges in daily disease management for both the child and parental caregiver, financial strain, and disruption of social activities. Thus, this qualitative study and the following sections aim to build on these results to provide actionable insights for both future research and patient support programs.

Reducing Persistent Psychological Strain in Parental Caregivers of Children with T1DM Experience

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This study showed that parental caregivers of children with T1DM were particularly susceptible to psychological stress during the early stages after their child's first T1DM diagnosis. These stressors manifested as recollections of negative emotions leading to emotional distress, including shock, sadness, and anxiety. Further, the challenges of repeat insulin injections and finger blood glucose monitoring in child posed not only technical challenges for non-medical professional caregivers, but also emotional distress in parental caregivers. Shortly after a child's diagnosis, many parental caregivers reported feelings of disbelief, resulting in catastrophic emotional disturbances linked to shock, fear, frustration, despair, and sadness. These findings are consistent with other quantitative psychological studies demonstrating posttraumatic stress disorder (PTSD) symptoms in caregivers[20,22-24]; however, the use of qualitative interview methods enables additional insights into the character of reflective perceptions of parental caregivers, and how such stress can be relieved. Our study suggests that the emotional effects of "invisibility" of the condition prior to diagnosis can trigger guilt and anxiety that exacerbate psychological stressors. Further, young age of the child and uncertainty of social impact can also exacerbate the psychological effects on the caregiver, leading to heightened anxiety and PTSD manifestations. In some cases, these stressors can lead to catastrophic emotional experiences occurred in the early stage of diagnosis and during a child's hospitalization, which is consistent with other research[25].

In particular, following the hospital discharge of a child with T1DM, parental caregivers in this study exhibited heightened emotions, characterized by poorly controlled worry, anxiety, sadness, stigma, annoyance, and guilt. During the course of our interviews, it emerged that worry, anxiety, and sorrow were closely linked to uncertainty of disease progression. This observation is consistent with prior studies that have shown parental caregivers of children with T1DM experience a heightened level of disease uncertainty compared to caregivers of other chronic disease states, which can exert adverse effects on the health and psychological condition of the parental caregivers and the children they care for[26]. Thus, medical staff should pay particular attention to these potential effects in parental caregivers.

Parental caregivers, in part due to their emotional bond with their child, are also affected by emotionally by perceived stigma. Stigma refers to a kind of inner shame caused by illness that is perceived a deficiency, which negatively affects patient psychology and can contribute noncompliance or delay of critical treatment and monitoring in T1DM[27]. During the interviews conducted in this study, some parents of children with T1DM expressed that diabetes would affect their child's future employment, marriage, and social standing, in some cases going so far as to hide their child's to avoid perceived discrimination. Stigma affects caregivers by playing on their guilt, which may be exacerbated by "causing" the child pain through blood tests and limiting activities or diet. Some parents also have limited scientific understanding of the illness, and perceive the disease to be a result of negligent in care that can further exacerbate feeling of guilt, anxiety, and depression in caregivers. Parent's persistent emotional distress affects their own physical and mental health, thereby affecting management of blood glucose

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control in their children[28]. Thus, the emotional state of the parental caregiver is of concern to medical staff treating children with T1DM.

As prior research has shown, the self-efficacy of parental caregivers in diabetes management is related to the effectiveness of blood glucose control[29]. In the interviews conducted in this study, parental caregivers emphasized expectations placed on the mother's role, and their increased sense of self-efficacy. Parents that perceived themselves as competent in the role of caregiver consistency experienced less emotional distress. Through analyzing interviews, this study found that the psychological burden of parents primarily derives from the following courses: (1) Pressure of blood glucose management in children, especially in diet management; (2) Children's physical and mental pain caused by insulin injections, blood glucose monitoring, and diet restrictions; (3) Mood changes in children due to illness; and (4) The impact of the disease on the future of the children. These insights can be used to design integrated patient management programs that consider both parental caregiver emotional health and the medical condition of the T1DM child.

Supporting the Transition of Parents into an Evolving Caregiver Role

Becoming a caregiver of child with T1DM is disruptive not only to the parent(s), but also to the family unit. Further, the emotional burden on parental caregivers is increased by an evolving need for autonomy over T1DM care as young children age. For younger children with T1DM, parental caregivers will need to dedicate substantial time and financial resources to their child's daily care, such as regular blood glucose measurement, injecting insulin, monitoring their diet and physical activities, and handling emergent issues. Common challenges in daily management include difficulty in blood glucose management, emotional management, parent-child conflict, and the transition from parental management to self-management. While technology has

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improved T1DM care through the use of insulin pumps and continuous blood glucose monitoring, often young children may not have access to these technologies or compliance may not be possible[30]. These changes in activities of daily living in the family unit also impact relationships between parents and children, can lead to conflict. Thus, additional support is needed in the community and clinical setting to support parents transitioning through the various stages of T1DM caregiver roles.

Parental caregivers of children with T1DM also face challenges in transitioning their role to give their child gained increased autonomy with age. In this study, it was apparent from interviews that, even at a young age, issues of the child's autonomy could affect the parent-child relationship and lead to family conflict. Studies have shown that in families experience conflicts in chronic disease care settings. In particular, children with T1DM and high levels of family conflict have been shown to have poorer blood glucose control and lower overall quality of life[31,32]. As young children grow into adolescents, these conflicts may become more common or escalate. Khandan (2018)[33] found that when children with T1DM reached the age of 8 to 11, their parents begin to transfer diabetes management responsibility to them, gradually transitioning from "parental responsibility" to "cooperative support." While parents have a high degree of control over their young child's medical care, they may require outside support for clinicians or the community in transitioning these responsibilities as their child enters adolescents. Appropriate mental health and community support may thus improve outcomes among these children and their caregivers and help to achieve an effective transition to self-management as these children enter adolescence.

Improving Financial and Social Support Systems for Parental Caregivers of Children with T1DM in China

In this study, parental caregivers of children with T1DM consistency reported a strain

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on household finances related to their child's care and disposable supplies, and a lack of social support. Similar to the results of other studies[34], medications and disposable devices used for long-term treatment place a substantial and ongoing burden on these families, often affecting housing, employment, and economic opportunities for middle- and low-income families. Financial burden can affect the physical and mental health of parental caregivers, also limit or delay selection of treatment options that can influence the T1DM child's long-term prognosis.

Further, the lack of social support and relative social isolation of caregivers, particularly those that reduces hours or left jobs to act as primary caregivers (most common among mothers), was consistently reported in this study. The lack of support systems was apparent from limited family social activities, which often negatively impacted the parental caregiver's emotional state. Further, compared to other developed regions, China has currently has a lack of diabetes nurses in kindergartens and primary and secondary schools. Thus, preschool and school-age children have to assume the responsibility of diabetes self-management during school hours. Furthermore, because of self-esteem issues or poor self-control, many parents we studied reported that their blood sugar control was not ideal during school. Therefore, we propose that we should, as a healthcare system, selectively learn from the successful experience of other countries and gradually implement training for school personnel and other personnel who come into contact with diabetic children to improve the social support system for children with diabetes.

Notably, this research is limited by the interpretation of the reviewers and coders. In particular, all interviewees and researchers were from a single hospital, which limits the generalizability of the findings of this study to a broader population. However, these insights provide greater depth than mere quantitative characterizations, and provide

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essential insights to improving both psychological and physical outcomes of children with T1DM and their parental caregivers.

Conclusions

Through a series of interviews that examined the perceptions of parental caregivers of children with T1DM, this qualitative study employs grounded theory methods to examine the emergent themes in these conversations, often anecdotally experiences by health care professionals. This research gives voice to the common challenges faces by parental caregivers as their young children are first diagnosed with T1DM and slowly gain autonomy for their own chronic disease management with age. This research demonstrated common themes of persistent psychological stress, difficulty managing changes in family function, challenges in daily disease management, challenges of excessive financial burden, and the impact of a lack of social support for parental caregivers. By characterizing these common perceptions and experiences, we can better prepare health care providers to support both the T1DM child and parental as they adapt to medical management of T1DM at different life stages, thereby improving home self-management capabilities.

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List of abbreviations

T1DM: Type 1 Diabetes Mellitus

QoL: Quality of life

GT: Grounded Theory

PTSD: posttraumatic stress disorder

IRB: Institutional Review Board

Declarations

Funding: No financial support was received for this study

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Authors' contributions: The study was supervised by Dr. Ling Fan. The study was performed by Huijuan Tong. Data were coded and interpreted by Dr. Feng Qiu and Dr. Huijuan Tong. The manuscript was written by Huijuan Tong and Ling Fan.

Ethics approval and consent to participate: This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board (IRB) of Shengjing Hospital, China Medical University, Shenyang, China (Approval no. 2018PS362K). All participants provided written informed consent prior to participating in interviews.

Consent for publication: Not applicable

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Table 1 Semi-Structured Interview Outline for Parents of Children Aged ≤14 with Type 1 Diabetes Mellitus (T1DM Caregiving Parents)

Question #	**Description**
1	Could you please talk about the situation when your child was first diagnosed with type 1 diabetes and your reaction at that time?
2	Could you please describe a day of caring for a child with type 1 diabetes?
3	Since your child was diagnosed with diabetes, what has been your biggest concern, or what is the most difficult issue you have had to deal with?
4	How do you help your child manage his/her diet?
5	How do you help your child manage his/her medication?
6	How do you help your child manage his/her activities or exercise?
7	How do you help your child manage his/her emotions?
8	How do you manage your own life while taking care of your child?
9	As a caregiver, what are your needs in caring for the child?
10	Do you think you are qualified for the role of caring for a child with type 1 diabetes?

Note: This outline has been translated from the original Mandarin Chinese version. All interviews were conducted in the local language of the investigator (Mandaring Chinese).

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Table 2 Characteristics of Parental Caregivers of T1DM Children (T1DM Caregiver Parents) Interviewed

Characteristic	**Interviewee (n = 20)**
Children	
Age (years), mean±SD	10.6±2.45
Onset age of T1DM, mean±SD	7.2±2.4
Insulin regimen, n (%)	
Insulin pump use	8 (40%)
Daily injections	12 (60%)
Gender, n(%)	
Male	7 (35%)
Female	13 (65%)
Parents	
Age(year), mean±SD	39.45±6.21
Gender, n (%)	
Male (self-identify as Father)	8(40%)
Female (self-identify as Mother)	12(60%)
Current employment status, n (%)	
Full-time	8 (40%)
Part-time	6 (30%)
Not working	6 (30%)
Highest education level, n (%)	
Junior high (middle) school or some high school	6 (30%)
High school diploma	6 (30%)

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Technical school (2-year degree or equivalent)	3 (15%)
Bachelor’s degree (4-year degree or equivalent)	5 (25%)
Monthly Income (CNY), n (%)	
< 3077	5 (25%)
3077 to -11428	9 (45%)
>11428	6 (30%)

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Table 3 Themes and Sub-themes Emerging from Interviews of Parental Caregivers of T1DM Children (T1DM Caregiver Parents)

Themes	**Subthemes**
Persistent psychological stress	(1) catastrophic emotional experience
	(2) emotional distress based in negative emotions
	(3) altered sense of self-efficacy
	(4) perceived increased responsibility for parenting
Family function changes	(1) changes in patterns of family life
	(2) changes in parental roles and functions
Challenges in daily management	(1) technical difficulties managing blood glucose
	(2) difficulties in regulating emotion
	(3) managing parent-child conflict
	(4) transition from parental management to self-management as the child ages
Excessive financial burden	(1) burden of disease treatment
	(2) changes in economic sources
Lack of social support system	(1) limited social activities
	(2) insufficient other support systems

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Characterizing Common Challenges Faced by Parental Caregivers of Children with Type 1 Diabetes Mellitus in Mainland China: A qualitative study

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Abstract

Objectives: Mental state of parental caregiver affects outcomes in children with Type 1 Diabetes Mellitus (T1DM). This study aimed to qualitatively examine perception of common challenges among parental caregivers of children with T1DM.

Setting: 45-60 minutes long semi-structured interviews were conducted with T1DM Parental Caregivers. Interview recordings were transcribed and coded in NVivo 11.0 to observe emergent themes.

Participants: Eligible T1DM Caregiving Parents (parent(s) and/or legal guardian(s)) were identified from caregivers attending visits with children hospitalized or assessed in the Pediatric Neuroendocrinology Department of Shengjing Hospital, China Medical University in Shenyang from January 2018 to June 2019.

Primary and secondary outcome measures: Not applicable.

Results: A total of 20 T1DM Caregiving Parents were interviewed, aged 30 to 53 years, including 7 fathers and 13 mothers, with their children mean age of 10.6±2.45 years. Content analysis revealed 5 common themes with 13 subthemes, including persistent psychological stress (catastrophic emotions, emotional distress, and altered self-efficacy), family function change (altered family life patterns and changes in parental role/function), challenges in daily management (technical challenges, emotional regulation, parent-child conflict, and transition of care autonomy from parent to child), financial burden (cost burden of treatment and altered family economics), and lack of social support (social activity limitations and insufficient support systems).

Conclusions: Period of emotional disturbance during initial diagnosis, psychological stresses of long-term caregiving, and conflict emerging from transition from parental to child responsibility all can cause psychological effects detrimental to parental caregivers and T1DM children. This work provides compelling evidence for the role of

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assessment and intervention in parental caregiver psychological and emotional wellbeing in diabetes care, as well as the need for improved social and school support for children with T1DM in China.

Keywords: Type 1 Diabetes Mellitus, Grounded Theory, Qualitative Methods, Caregiving, Diabetes Care, Psychological Perceptions

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Strengths and limitations of this study

1. This is the first study, which describes the conditions and consequences of young children with T1DM relying on parental caregivers for disease management in China.
2. This study demonstrates that period of emotional disturbance during initial diagnosis, psychological stresses of long-term caregiving, and conflict emerging from transition for parental to child responsibility can cause psychological effects detrimental to parental caregivers and T1DM children.
3. This study provides compelling evidence for the role of assessment and intervention in parental caregiver psychological and emotional wellbeing in diabetes care.
4. This study is limited by the interpretation of the reviewers and coders.
5. This is a single-center study, with limited generalizability of the findings, and a further multicenter study was needed.

Introduction

Type 1 Diabetes Mellitus (T1DM) is a common enough chronic disease in children, and both the parental caregiver as well as the child diagnosed with T1DM must partake on management of disease associated tasks, with underlying financial, emotional, and social impact on the family unit[1]. With the incidence of T1DM increasing by 2% to

5% each year worldwide[2], an increasing number of families with young children are influenced by its burden. Although the incidence of T1DM in China is lower than that in Europe or the United States, being currently 5.6 per 100,000 live births[3], China ranks fourth among countries for T1DM occurrence — and the number of cases is increasing each year[4]. However, rural communities in China generally have fewer resources and growing number of T1DM cases outside of urban centers would eventually increase the strain on Chinese parental caregivers. Thus, examining the situation of middle- and low-income parents of children with T1DM in China is essential to improving resources for T1DM care and long-term outcomes.

Management of T1DM in children involves changes in daily living activities that affect not only the child receiving care but also the caregiver, including responsibility to ensure continuous glucose monitoring (4 or more times per day) and insulin injection using an insulin pump or injecting insulin multiple times a day, as well as tracking and calculating daily carbohydrate intake and physical activity levels important to prevention of hypoglycemic and hyperglycemic episodes[5, 6]. Majority of children with T1DM under age of 13 are unable to self-manage their T1DM care, and instead rely heavily on their parental caregiver for disease management[7]. Treatment for children with T1DM is aimed at ensuring stable blood glucose levels, minimizing occurrence of potentially severe hypoglycemic events, and preventing long-term complications of diabetes as the child grows[8]. These responsibilities presumably place immense psychological and financial stress on parental caregivers.

Owning to the relatively lower incidence of T1DM outside of urban centers in China, the emotional toll, financial burden, and social isolation experienced by parental caregivers of young children with T1DM can be immense. Despite improvements in T1DM medications and treatment technologies, many children still experience adverse

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health effects due to invasive procedures or ineffective blood glucose control[9]. Recent research suggests that, more than 58.6% of children with T1DM in China do not achieve sustained hemoglobin control (glycosylated hemoglobin lower than 7.5%)[10]. This can lead to complications, that have adverse impact on the child's growth and long-term health, and place significant burden on caregivers and the family unit. Thus, there is a need to study T1DM care, and its impact on parental caregivers, through a social lens.

Rankin et al. (2018)[1] used qualitative methods to examine the strategies and motivations of children with T1DM and their caregivers, providing insights into how diabetes management can be improved. Other researchers have also demonstrated that successful disease management of children with T1DM not only requires the children to manage their individual health, but also requires their cooperation with caregivers who share the responsibility for the child's medical management[11]. These burdens can, however, result in caregiving parents of children with T1DM feeling isolated and helpless when faced with the challenges of chronic disease management. Psychologically, caregivers may manifest a sense of self-doubt, guilt, or anxiety, and many of them experience traumatic initial confusion as they try to integrate these new responsibilities into their family's routine when their child is first diagnosed[12]. These feelings may be transient or persist, and may be exacerbated if a child experiences hypoglycemic events or other emergency situations that contributes to caregiver trauma and anxiety[13-15]. Understanding the experiences of parental caregivers of children with T1DM could greatly improve clinical and social interventions to help parents adapt to the role of caregiver, and achieve optimal health outcomes for their children. However, current research on children with T1DM in China is primarily limited to quantitative studies on the quality of life (QoL)[15], psychological state[16] and coping

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style of the children or their parents[17].

Qualitative research methodologies can provide actionable insights into the psychological state, behaviors, and motivations of patients and caregivers managing T1DM[1]. This study employs qualitative methods to examine the perceptions of parental caregivers of young children (aged 14 or younger) with T1DM in China, providing insights into the key challenges as caregivers transition from complete management of young children with T1DM to an older child with increasing autonomy over his or her medical care. Thus, this research is designed to provide actionable insights for improving social support and management of these patients, in a holistic context that considers the parental caregiver and family unit.

Methods

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Study Population and Design

Qualitative research methods were employed to examine social, emotional, and experiential perceptions of parent(s) and/or legal guardian(s) with children diagnosed with T1DM, referred to as T1DM Caregiving Parent for purposes of this article. Synchronous, in-person, semi-structured interviews were conducted to collect qualitative data, and emergent heuristic content analysis was subsequently performed on transcripts. Eligible T1DM Caregiving Parents were identified from caregivers attending visits with children hospitalized or assessed in the Pediatric Neuroendocrinology Department of Shengjing Hospital, China Medical University in Shenyang from January 2018 to June 2019.

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To be eligible for participation in study interview, T1DM Caregiving Parents were required to (1) be the parent and/or legal guardian of a child 14 years of age or younger with diagnosed T1DM, and (2) be a primary caregiver during at least 6 months of continuous care for child being treated for T1DM during this period[18] T1DM Caregiving Parents were considered ineligible to participate in interviews if (1) the child with T1DM also experienced other significant comorbidities or chronic diseases; (2) the child with T1DM was considered to require immediate medical care or treatment and the study could pose an undue burden on the patient or caregiver; (3) T1DM Caregiving Parent was unable to communicate fluently in the local language of the investigator (Mandarin Chinese).

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board (IRB) of Shengjing Hospital, China Medical University, Shenyang, China (Approval no. 2018PS362K). All participants provided written informed consent prior to participating in interviews.

Sampling Methods and Process

Purposive nonprobability sampling was used, in which eligible T1DM Caregiving Parents were approached for participation as they visited clinic. To ensure a representative sample, the heterogeneity of sample selection was expanded for T1DM Caregiving Parent age, marital status, education level, and T1DM child age and disease course. The study was discontinued when qualitative data reached saturation, which was expected to occur between 15 and 20 interviews, as previously described[19, 20] When the number of interviews reached 20, the data in our research was saturated, and no new information was obtained, so sampling was terminated.

Data Collection

An IRB-approved semi-structured interview outline was used to ensure consistency

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while performing interviews. The interview structure was based on the theory of individual and family self-management[21], and formulated through expert evaluation of the research purpose, population, and existent body of literature. The outline used in interviews is shown in **Table 1**. The planned duration of the interview was 45 to 60 minutes.

Upon arrival at the clinical site, the head nurse of the clinical unit familiar with the T1DM Caregiving Parent met the interviewee, led them to the interview site, and made introductions. Prior to the start of the interview, the interviewer explained the purpose, significance, methods, rights of the interviewee, and privacy protection measures. Written informed consent was then obtained before starting each interview.

The interview location was selected as audio visual classroom located in the Pediatric Neuroendocrinology Ward. This location was selected for the quiet environment, free of distractions. Interviews were conducted by the authors, who were provided with training on semi-structured interviews and use of neutral, objective, and non-leading language during the interview to maximize data integrity.

Data Transcription and Coding

Each interview was recorded using audio recording devices, and digitally transcribed asynchronously (with 48 hours after each interview) by the researchers. Transcripts were recorded in MS Word (Microsoft, USA), and verified by a second researcher. To ensure data integrity, interviewees were provided with a copy of their interview transcript and allowed to suggest corrections, which, if appropriate, were assessed and integrated by the researchers upon review of the original recording.

Heuristic coding was performed using emergent grounded theory methods[20] manually using transcripts imported into NVivo 11.0 (QSR International, USA) using manual code to summarize text data, and identify and refine themes. Coding was

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verified by a second researcher, the numbers were used to identify the interviewees in place of their real names, DM1-DM20. Emergent themes and subthemes were identified using a grounded theory approach.

Data Analysis and Reporting

Textual coding results in NVivo 11.0 were reported as counts and percentages (data not shown) and themes/sub-themes were presented descriptively using qualitative analysis methods. All analyses were performed in the local language of the interview conduct (Mandarin Chinese), and the data were analyzed and collected simultaneously. The theme of the interviews was extracted using content analysis methodology by way of three-grade coding. Final results were translated to English, and all translations were performed by the researchers to ensure integrity of translations.

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Results

Participant Characteristics

Saturation was reached when 20 T1DM Caregiving Parents (N = 20) completed interviews. Interviewed T1DM Caregiving Parents included 7 fathers and 13 mothers (gender roles were self-identified by the interviewee), aged 30 to 53 years, with their children mean age of 10.6±2.45 years. Of these patients, 8 were caregivers of children with T1DM that were treated with insulin pumps, and 12 were caregivers of children with T1DM that were treated with subcutaneous injections. Socio-demographic information for T1DM Caregiving Parents completing interviews and demographic and clinical condition of their children are summarized in **Table 2**.

By analyzing the transcripts of interviews, five emergent themes were observed consistently throughout the interview data: (1) persistent psychological stress; (2) family function changes; (3) challenges in daily management; (4) excessive economic burden; (5) lack of support system. All 13 subthemes within these 5 themes, are summarized in **Table 3**. The themes/sub-themes are further characterized below.

Theme of Persistent Psychological Stress

Persistent psychological stress was identified as prominent theme across interviews, with four key sub-themes emerging from coding:

(1) Catastrophic Emotional Experience

In acute period following diagnosis, parents often experienced emotions that can be described as catastrophic, including shock, fearfulness, frustration, hopelessness, sadness, and feelings that disaster is imminent.

Interviewee DM2: "When the doctor told me that my child was diabetic, I felt like [I was] struck by lightning and the sky was falling. My child's life is basically over.”

(2) Emotional Distress Based in Negative Emotions

Negative emotions observed in T1DM Caregiver Parents primarily included continual worry, anxiety, sadness, stigma, annoyance, and guilt. Worry was embodied in anxiety and sadness, often with connections to the uncertainty of disease progression in their child. Some parents also experienced symptoms of worry and invasive thoughts about the potential for their children to be discriminated in the future because of their illness, leading some to even report hiding their child’s illness in common social contexts. Further, parents reported feeling guilt linked to social isolation and dietary restrictions experienced by their child, etiology of illness (often linked to limited clinical understanding of T1DM), or feeling of being “at fault” for their child’s condition.

Interviewee DM2: “It’s still like a sword hanging over my head. I don’t know when the complications will come. I live with fear every day."

Interviewee DM6: I don’t want people around to know that my child has diabetes. Diabetes is an undead cancer. Thinking about it in another way, who wants his child to

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marry a diabetic in the future? You may only have to marry someone who also has diabetes. My child doesn't want her classmates to know that she is different from others."

Interviewee DM3: "My thoughts are that he is too young and suffers too much. He has to get injections and blood tests every day, and his fingers are pierced constantly. As a parent, I feel like a failure. I have not taken good care of my child and have been busy with work. I feel like I neglect taking care of him."

(3) Altered Sense of Self-Efficacy

T1DM Caregiver Parents also showed self-doubt owing to lack of experience in chronic disease care. In the most extreme cases, these feelings manifest as a severe lack of self-compassion, wherein parents expressed doubt in their ability to competently care for their child.

Interviewee DM6: "Taking care of [my daughter], it's not that I think I can or can't, but that I must be able to do. It's like a parent's obligation. If I can't, what else can she do? It's not something I can or can't do. It's something I must be able to do."

(4) Perceived Increased Responsibility for Parenting

T1DM Caregiver Parents reported perceiving a heavier burden of responsibility to manage their child's disease and remain hypervigilant, in particular for young children with T1DM not capable of self-managing. Parents perceive that, compared to children without T1DM, both parents and children bore additional responsibilities.

Interviewee DM19: "Now our child is too young to take care of herself. As parents, we are duty-bound, we have to be good supervisors. We supervise our child's diet, exercise, blood glucose testing and injections. Although we are not professionals, we will be dedicated to protecting our child's health. "

Altered Facility Function

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Changes in family life included two prominent subthemes:

(1) Changes in Patterns of Family Life

Changes in routine patterns of daily living within the family unit were consistently reported by T1DM Caregiver Parents. These changes included changes in family activities designed to assist children in adapting to their life after T1DM diagnosis. On one hand, parents reported striving to retain normalcy for their children; however, the child's T1DM was also often reported to be disruptive to others, particularly other children, in the family unit. Parents also reported aiming to incorporate blood glucose measurement in routine daily living activities of the family unit, with mixed success.

Interviewee DM16: "It is inevitable that [when living with a child with T1DM] you can't be the same as other families. We have to consider our child's physical strength and whether [he] can eat regularly. Especially when faced with a table full of good food, it is uncomfortable for the child to see others eating."

Interviewee DM18: "Now we guide our child to think that measuring blood glucose and injecting insulin is a routine in life, just like showers before bed. We don't want our child to feel that injecting insulin before meals is a burden."

(2) Changes in Parental Role and Function

T1DM Caregiver Parents consistently reported that they perceived differences between their "normal" role and function compared with their prior lifestyle before their child's diagnosis. Specifically, T1DM Caregiver Parents expressed that their child's diagnosis affected their future career planning, life focus, and goals, and often resulting in a greater amount of time spent tending medical needs of their child.

Interviewee DM5: "Now I rarely focus my energy on the company [I work for], just get off work as soon as possible. I used to leave early and return late to make money. Now I quit my job and found a new one that can make a living while taking care of my child.

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When she is on vacation, so am I."

In some cases significant housing and job/school changes are made to accommodate the child's T1DM care.

Interviewee DM14: "My family is in the countryside, but our child comes to a school in the city. Since our child has the disease, diabetes, and cannot live in school, I have to accompany him to study. My child and I rented a house near the school, which is convenient for me to take care of him, and we will return to the countryside during vacation, where his father works.

Challenges in Daily Management Theme

Challenges in daily management were consistency reported by T1DM Caregiver Parents, including:

(1) Technical Difficulties in Blood Glucose Management

T1DM Caregiver Parents reported technical difficulties in blood glucose management, including unsatisfactory or irregular blood glucose levels, primarily associated with dietary control, exercise compliance, untimely blood glucose monitoring, and insulin injection dosage adjustment. Parents expressed that lack of self-management, often owning to social and educational obligations, was often a key concern.

Interviewee DM3: "He is in the second grade of junior high school. There is a lot of tutoring outside school. He has to get up at 5:30 in the morning to study and finish school at 5:30 in the evening. If goes to the tutoring class, he returns at 8:30. There is no time to exercise. At school, his blood glucose control was poor [but] it is impossible to ask him to leave school to take measurements before and after meals."

(2) Emotional Regulation and Managing Parent-Child Conflict

In addition to the regulation of T1DM Caregiver Parents' own emotions, interviewees also reported difficulty in assessing and managing their child's emotional and

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psychological needs.

Interviewee DM14: "[My daughter with T1DM] feels that if her classmates know she is sick and can’t be cured, she will be inferior to others. Often it was lunch at noon, and she went to the toilet to get an injection, because she is afraid of being discriminated against by her classmates or something. Our child’s self-esteem is strong, so she ran to the toilet for injections; at that time, if another child went to the toilet, she would be frightened, remove the needle and hurriedly put it away. She would not press and was still bleeding. As a parent, I feel distressed, but I don’t know how to help the child to feel better.”Interviewees consistently reported that parent-child conflict stemmed from inability to communicate effectively and perception of their children’s poor compliance with disease management. As children age and their sense of autonomy increases, parents reported difficulty in transitioning to stages where their child exerts greater autonomy over their T1DM care and monitoring. In particular, interviewees reported resistance from their child, and perceptions that the child felt controlled by the parent’s actions.

Interviewee DM20: "I understand that the child is also upset and there is no place to vent. I restrict her diet and control her blood glucose measurements. How can she not resist psychologically? I feel that I can't get into her heart, I don't know how to get along with her."

(3) Transition from Parental Management to Self-Management as the Child Ages

With changes in their child’s growth and developmental stage, the roles and function of children and parents in T1DM management shifts. However, premature transfer of diabetes management tasks to children with T1DM is now considered a factor leading to poor blood glucose control. Many T1DM Caregiver Parents expressed uncertainty or frustration on transition timing.

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Interviewee DM15: "In the first year, we helped her with her insulin injections, and then she did it by herself for the next two years. The blood glucose monitoring at night was not done, so the glucose control was not good. Such an old child is really difficult to manage, half-sensible but not sensible."

Excessive Financial Burden Theme

T1DM Caregiver Parents consistently reported the excessive financial burden of caring for a child with T1DM, including high cost of treatment. This burden was often cited as a factor for job and educational changes, affecting family member circumstances. Due to the long-term nature of treatment, medications and injection supplies are consumable items with sustained cost impact. Furthermore, caring for a young child with T1DM often requires care around the clock, with some parents reporting that one of the parents gave up employment, changed employment, or reduced hours to provide adequate care for their child, often decreasing household income and adding further financial stress to middle- and low-income families.

Interviewee DM2: "Using an insulin pump is a great economic pressure. It costs nearly 20,000 CNY [about 3000 USD] a year. One tube is normally more than 110 CNY [about 17 USD]. I will buy some during sales and let my friends buy some more from other channels. A tube can be used for three days. It costs nearly 20,000 CNY [about 3000 USD] a year."

Lack of Social Support Systems Theme

The lack of support system primarily includes limited social activities and insufficient social support system, as described below:

(1) Limited Social Activities

At present, the family structure in China is dominated by a typical nuclear family, and children are generally a primary focus of the family unit. Once a child is diagnosed with

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T1DM, T1DM Caregiver Parents reported feeling disruption in the social activities of the family unit. In particular, mothers in the interview often left their employment, changed careers, or reduced hours to be able to care for their child with T1DM, thus narrowing their social circle to the immediate family members. This transition can result in social isolation and limit normal social activities of the parent.

Interviewee DM10: "Since my child had a ketosis coma, I have never dared to relax again. I have lost myself. Every day in the year, there are no more visits to relatives or friends."

(2) Insufficient Other Support Systems

Insufficient systems of social support were a common concern of T1DM Caregiver Parents, especially those of children reaching school age and assuming autonomy over their care during school hours.

Interviewee DM12: "Unlike other countries, our children do not have diabetes nurses in school. When the child is at school, every time the teacher calls, I am terrified, always scared that something bad will happen. If the child's blood glucose is low, does the teacher know how to handle it? Will it be delayed?"

Discussion

This study aimed to qualitatively examine perception of common challenges among parental caregivers of children with T1DM. Using Grounded Theory (GT), a method based in social science research, [20-21] the researchers examined and consolidated emergent themes from interview transcripts. In this study, parental caregivers of T1DM children consistently reported persistent psychological stress, changes in routine functions of the family unit, challenges in daily disease management for both the child and parental caregiver, financial strain, and disruption of social activities. Thus, this

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qualitative study and the following sections aim to provide actionable insights for both future research and patient support programs.

Reducing Persistent Psychological Strain in Parental Caregivers of Children with T1DM Experience

This study showed that parental caregivers of children with T1DM were particularly susceptible to psychological stress during the early stages after their child's first T1DM diagnosis. These stressors manifested as recollections of negative emotions leading to emotional distress, including shock, sadness, and anxiety. Further, repeat insulin injections and finger blood glucose monitoring in child posed not only technical challenges for non-medical professional caregivers, but also emotional distress in parental caregivers. Shortly after a child's diagnosis, many parental caregivers reported feelings of disbelief, resulting in catastrophic emotional disturbances linked to shock, fear, frustration, despair, and sadness. These findings are consistent with other quantitative psychological studies demonstrating posttraumatic stress disorder (PTSD) symptoms in caregivers[20, 22-24]; however, the use of qualitative interview methods enables additional insights into the character of reflective perceptions of parental caregivers, and how such condition can be relieved. Our study suggests that the emotional effects of "invisibility" of the T1DM prior to diagnosis can trigger guilt and anxiety that exacerbate psychological stressors. Further, young age of the child and uncertainty of social impact can also exacerbate the psychological effects on the caregiver, leading to heightened anxiety and PTSD manifestations. In some cases, these stressors can lead to catastrophic emotional experiences occurred in the early stage of diagnosis and during a child's hospitalization, which is consistent with other research[25].

In particular, following the hospital discharge of a child with T1DM, parental

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caregivers in this study exhibited heightened emotions, characterized by poorly controlled worry, anxiety, sadness, stigma, annoyance, and guilt. During the course of our interviews, it emerged that worry, anxiety, and sorrow were closely linked to uncertainty of disease progression. This observation is consistent with prior studies that have shown parental caregivers of children with T1DM experience a heightened level of disease uncertainty compared to caregivers of other chronic states, which can exert adverse effects on the health and psychological condition of the parental caregivers and the children they care for[26]. Thus, medical staff should pay particular attention to these potential effects in parental caregivers.

Parental caregivers, in part due to their emotional bond with their child, are also affected emotionally by perceived stigma. Stigma refers to a kind of inner shame caused by illness that is viewed as a deficiency, which negatively affects patient psychology and can contribute noncompliance or delay of critical treatment and monitoring in T1DM[27]. During the interviews conducted in this study, some parents of children with T1DM expressed that diabetes would affect their child's future employment, marriage, and social standing, in some cases going so far as to hide their child's condition to avoid perceived discrimination. Stigma affects caregivers by playing on their guilt, which may be exacerbated by "causing" the child pain through blood tests and limiting activities or diet. Some parents also have limited scientific understanding of the illness, and perceive the disease to be a result of neglect in care that can further exacerbate feeling of guilt, anxiety, and depression. Parent's persistent emotional distress affects their own physical and mental health, thereby affecting management of blood glucose control in their children[28]. Thus, the emotional state of the parental caregiver is of concern to medical staff treating children with T1DM.

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As prior research has shown, the self-efficacy of parental caregivers in diabetes management is related to the effectiveness of blood glucose control[29]. In the interviews conducted in this study, parental caregivers emphasized expectations placed on the mother's role, and their increased sense of self-efficacy. Parents that perceived themselves as competent in the role of caregiver consistency experienced less emotional distress. Through analyzing interviews, this study found that the psychological burden of parents primarily derives from the following courses: (1) Pressure of blood glucose management in children, especially in diet management; (2) Children's physical and mental pain caused by insulin injections, blood glucose monitoring, and diet restrictions; (3) Mood changes in children due to illness; and (4) The impact of the disease on the future of the children. These insights can be used to design integrated patient management programs that consider both parental caregiver emotional health and the medical condition of the T1DM child.

Supporting the Transition of Parents into an Evolving Caregiver Role

Becoming a caregiver of child with T1DM is disruptive not only to the parent(s), but also to the family unit. Furthermore, the emotional burden on parental caregivers is increased by an evolving need for autonomy over T1DM care as children age. For younger children with T1DM, parental caregivers will need to dedicate substantial time and financial resources to their child's daily care, such as regular blood glucose measurement, injecting insulin, monitoring their diet and physical activities, and handling emergent issues. Common challenges in daily management include difficulty in blood glucose management, emotional management, parent-child conflict, and the transition from parental management to self-management. While technology has improved T1DM care through the use of insulin pumps and continuous blood glucose monitoring, often young children may not have access to these technologies or

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compliance may not be possible[30]. These changes in activities of daily living in the family unit also impact relationships between parents and children, can lead to conflict. Thus, additional support is needed in the community and clinical setting to support parents transitioning through the various stages of T1DM caregiver roles.

Parental caregivers of children with T1DM also face challenges in transitioning their role to allow their child increased autonomy with age. In this study, it was apparent from interviews that, even at a young age, issues of the child's autonomy could affect the parent-child relationship and lead to family conflict. Previous studies have shown that families often experience conflicts in chronic disease care setting. In particular, children with T1DM and high levels of family conflict have been shown to have poorer blood glucose control and lower overall quality of life[31, 32]. As young children grow into adolescents, these conflicts may become more common or escalate. Khandan (2018)[33] found that when children with T1DM reached the age of 8 to 11, their parents begin to transfer diabetes management responsibility to them, gradually transitioning from "parental responsibility" to "cooperative support." While parents have a high degree of control over their young child's medical care, they may require outside support from clinicians or the community in transitioning these responsibilities as their child enters adolescents. Appropriate mental health and community support may thus improve outcomes among these children and their caregivers and help to achieve an effective transition to self-management as these children enter adolescence.

Improving Financial and Social Support Systems for Parental Caregivers of Children with T1DM in China

In this study, parental caregivers of children with T1DM consistently reported a strain on household finances related to their child's care and disposable supplies, and a lack of social support. In the majority of cases, discussed in the present study, expenses were

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covered by insurance only during hospital stay, but after discharge the expenses were paid by parents/guardians. Insulin medication was also partly covered by health insurance, but the reimbursement rate varied depending on the type of health insurance (up to 90%). Similar to the results of other studies[34], medications and disposable devices used for long-term treatment place a substantial and ongoing burden on these families, often affecting housing, employment, and economic opportunities for middle- and low-income families. Financial burden can affect the physical and mental health of parental caregivers, also limit or delay selection of treatment options that can influence the T1DM child's long-term prognosis.

Furthermore, the lack of social support and relative social isolation of caregivers, particularly those that reduces hours or left jobs to act as primary caregivers (most common among mothers), was consistently reported in this study. The lack of support systems was apparent from limited family social activities, which often negatively impacted the parental caregiver's emotional state. Compared to other developed regions, China currently has a lack of diabetes nurses in kindergartens and primary or secondary schools. Thus, preschool and school-age children have to assume the responsibility of diabetes self-management during school hours. In addition, because of self-esteem issues or poor self-control, many parents in this study reported that blood sugar control was not ideal during school. Therefore, we propose that we should, as a healthcare system, selectively learn from the successful experience of other countries[35] and gradually implement training for school personnel and other personnel who come into contact with diabetic children to improve the social support system for children with diabetes.

Notably, this research is limited by the interpretation of the reviewers and coders. In particular, all interviewees and researchers were from a single hospital, which limits the generalizability of the findings to a broader population. However, these insights provide greater depth than mere quantitative characterizations, and may aid in improving both psychological and physical outcomes of children with T1DM and their parental caregivers.

Conclusions

Through a series of interviews that examined the perceptions of parental caregivers of children with T1DM, this qualitative study employs grounded theory methods to examine the emergent themes in these conversations, often anecdotally experiences by health care professionals. This research gives voice to the common challenges faces by parental caregivers as their young children are first diagnosed with T1DM and slowly gain autonomy for their own chronic disease management with age. This research demonstrated common themes of persistent psychological stress, difficulty managing changes in family function, challenges in daily disease management, challenges of excessive financial burden, and the impact of a lack of social support for parental caregivers. By characterizing these common perceptions and experiences, we can better prepare health care providers to support both the T1DM child and parental as they adapt to medical management of T1DM at different life stages, thereby improving home self-management capabilities.

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List of abbreviations

T1DM: Type 1 Diabetes Mellitus

QoL: Quality of life

GT: Grounded Theory

PTSD: posttraumatic stress disorder

IRB: Institutional Review Board

Declarations

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Table 1 Semi-Structured Interview Outline for Parents of Children Aged ≤14 with Type 1 Diabetes Mellitus (T1DM Caregiving Parents)

Question #	**Description**
1	Could you please talk about the situation when your child was first diagnosed with type 1 diabetes and your reaction at that time?
2	Could you please describe a day of caring for a child with type 1 diabetes?
3	Since your child was diagnosed with diabetes, what has been your biggest concern, or what is the most difficult issue you have had to deal with?
4	How do you help your child manage his/her diet?
5	How do you help your child manage his/her medication?
6	How do you help your child manage his/her activities or exercise?
7	How do you help your child manage his/her emotions?
8	How do you manage your own life while taking care of your child?
9	As a caregiver, what are your needs in caring for the child?
10	Do you think you are qualified for the role of caring for a child with type 1 diabetes?

Note: This outline has been translated from the original Mandarin Chinese version. All interviews were conducted in the local language of the investigator (Mandaring Chinese).

Table 2 Characteristics of Parental Caregivers of T1DM Children (T1DM Caregiver Parents) Interviewed

Characteristic	**Interviewee (n = 20)**
Children	
Age (years), mean±SD	10.6±2.45
Onset age of T1DM, mean±SD	7.2±2.4
Insulin regimen, n (%)	
Insulin pump use	8 (40%)
Daily injections	12 (60%)
Gender, n(%)	
Male	7 (35%)
Female	13 (65%)
Parents	
Age(year), mean±SD	39.45±6.21
Gender, n (%)	
Male (self-identify as Father)	8(40%)
Female (self-identify as Mother)	12(60%)
Current employment status, n (%)	
Full-time	8 (40%)
Part-time	6 (30%)
Not working	6 (30%)
Highest education level, n (%)	
Junior high (middle) school or some high school	6 (30%)
High school diploma	6 (30%)

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Technical school (2-year degree or equivalent)	3 (15%)
Bachelor’s degree (4-year degree or equivalent)	5 (25%)
Monthly Income (CNY/USD), n (%)	
< 3077/500	5 (25%)
3077-11428/500-1700	9 (45%)
>11428/1700	6 (30%)

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Table 3 Themes and Sub-themes Emerging from Interviews of Parental Caregivers of T1DM Children (T1DM Caregiver Parents)

Themes	Subthemes
Persistent psychological stress	(1) catastrophic emotional experience (2) emotional distress based in negative emotions (3) altered sense of self-efficacy (4) perceived increased responsibility for parenting
Family function changes	(1) changes in patterns of family life (2) changes in parental roles and functions
Challenges in daily management	(1) technical difficulties managing blood glucose (2) difficulties in emotional regulation and managing parent-child conflict (3) transition from parental management to self-management as the child ages
Excessive financial burden	(1) burden of disease treatment (2) changes in economic sources
Lack of social support system	(1) limited social activities (2) insufficient other support systems

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Characterizing Common Challenges Faced by Parental Caregivers of Children with Type 1 Diabetes Mellitus in Mainland China: A qualitative study

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Abstract

Objectives: Mental state of parental caregiver affects outcomes in children with Type 1 Diabetes Mellitus (T1DM). This study aimed to qualitatively examine perception of common challenges among parental caregivers of children with T1DM.

Setting: 45-60 minutes long semi-structured interviews were conducted with T1DM Parental Caregivers. Interview recordings were transcribed and coded in NVivo 11.0 to observe emergent themes.

Participants: Eligible T1DM Caregiving Parents (parent(s) and/or legal guardian(s)) were identified from caregivers attending visits with children hospitalized or assessed in the Pediatric Neuroendocrinology Department of Shengjing Hospital, China Medical University in Shenyang from January 2018 to June 2019.

Primary and secondary outcome measures: Not applicable.

Results: A total of 20 T1DM Caregiving Parents were interviewed, aged 30 to 53 years, including 7 fathers and 13 mothers, with their children mean age of 10.6±2.45 years. Content analysis revealed 5 major themes with 13 subthemes, including persistent psychological stress (catastrophic emotions, emotional distress, and altered self-efficacy), family function change (altered family life patterns and changes in parental role/function), challenges in daily management (technical challenges, emotional regulation, parent-child conflict, and transition of care autonomy from parent to child), financial burden (cost burden of treatment and altered family economics), and lack of social support (social activity limitations and insufficient support system).

Conclusions: Period of emotional disturbance during initial diagnosis, psychological stresses of long-term caregiving, and conflict emerging from transition from parental to child responsibility all can cause psychological response detrimental to parental

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caregivers and T1DM children. This work provides compelling evidence for the role of assessment and intervention in parental caregiver psychological and emotional wellbeing in diabetes care, as well as for the necessity of improved social and school support for children with T1DM in China.

Keywords: Type 1 Diabetes Mellitus, Grounded Theory, Qualitative Methods, Caregiving, Diabetes Care, Psychological Perceptions

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Strengths and limitations of this study

1. This is the first qualitative study, which describes the conditions and consequences of young children with T1DM relying on parental caregivers for disease management in China.
2. Each interview performed in this study took 45-60 minutes, with structure based on the theory of individual and family self-management, and formulated through expert evaluation of the research purpose, population, and existent body of literature.
3. To provide compelling evidence, heuristic content analysis was performed using grounded theory methods in order to summarize text data, and identify and refine emergent themes.
4. This study is limited by the interpretation of the reviewers and coders.
5. This is a single-center study, with limited generalizability of the findings, and a further multicenter study was needed.

Introduction

Type 1 Diabetes Mellitus (T1DM) is a common enough chronic disease in children, and both the parental caregiver and the child diagnosed with T1DM must learn how to manage the disease associated tasks, with underlying financial, emotional, and social impact on the family unit[1]. With the incidence of T1DM increasing by 2% to 5% each year worldwide[2], an increasing number of families with young children are influenced by its burden. Although the incidence of T1DM in China is lower than that in Europe or the United States, being currently 5.6 per 100,000 live births[3], China ranks fourth in the world for T1DM occurrence — and the number of cases is increasing each year[4]. In addition, rural communities in China generally have fewer resources and growing number of T1DM cases outside of urban centers would eventually increase the strain on Chinese parental caregivers. Thus, examining the situation of middle- and low-income parents of children with T1DM in China is essential to improve T1DM care and long-term outcomes.

Management of T1DM in children involves changes in daily living activities that affect not only the child receiving care but also the caregiver. That includes continuous glucose monitoring (4 or more times per day), ensuring insulin injections via insulin pump or injecting insulin multiple times a day, tracking and calculating daily carbohydrate intake as well as physical activity levels important to prevention of hypoglycemic and hyperglycemic episodes[5 6]. Majority of children with T1DM under age of 13 are unable to self-manage their T1DM care, and instead rely heavily on their parental caregiver for disease management[7]. Treatment for children with T1DM is aimed at ensuring stable blood glucose levels, minimizing occurrence of potentially severe hypoglycemic events, and preventing long-term complications of diabetes as the child grows[8]. These responsibilities presumably place immense psychological and financial stress on parental caregivers.

Owning to the relatively lower incidence of T1DM outside of urban centers in China, the emotional toll, financial burden, and social isolation experienced by parental caregivers of young children with T1DM can be immense. Despite improvements in

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T1DM medications and treatment technologies, many children still experience adverse health effects due to invasive procedures or ineffective blood glucose control[9]; more than 58.6% of children with T1DM in China do not achieve sustained hemoglobin control (glycosylated hemoglobin lower than 7.5%)[10], which leads to complications, that have adverse impact on the child's growth and long-term health, and place significant burden on caregivers and the family unit. This justifies a necessity to study T1DM care and its impact on parental caregivers through a social lens.

Previously Rankin et al. (2018)[1] used qualitative methods to examine the strategies and motivations of children with T1DM and their caregivers, providing insights into how diabetes management can be improved. Other researchers have also demonstrated that successful disease management of children with T1DM not only requires the children to manage their individual health, but also requires their cooperation with caregivers who share the responsibility for the child's medical management[11]. These burdens can, however, result in caregiving parents of children with T1DM feeling isolated and helpless when faced with the challenges of chronic disease management. Psychologically, caregivers may manifest a sense of self-doubt, guilt, or anxiety, and many of them experience traumatic initial confusion as they try to integrate these new responsibilities into their family's routine when their child is first diagnosed[12]. These feelings may be transient or persistent, and exacerbate if a child experiences hypoglycemic events or other emergency situations that contributes to caregiver trauma and anxiety[13-15]. Understanding the experiences of parental caregivers of children with T1DM could greatly improve clinical and social interventions, help parents adapt to the role of caregiver, and achieve optimal health outcomes for T1DM children. However, current research on the topic in China is

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primarily limited to quantitative studies on the quality of life (QoL)[15], psychological state[16] and coping style of the children or their parents[17].

Qualitative research methodologies can provide actionable insights into the psychological state, behaviors, and motivations of patients and caregivers who manage T1DM[1]. This study employs qualitative methods to examine the perceptions of parental caregivers of young children (aged 14 or younger) with T1DM in China, their key challenges as caregivers during transition from full management of young children with T1DM to an older child with increasing autonomy over his or her medical care. Thus, present research is designed to provide actionable insights for improving social support and management of these patients, in a holistic context that considers the parental caregiver and family unit.

Methods

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Study Population and Design

Qualitative research methods were employed to examine social, emotional, and experiential perceptions of parent(s) and/or legal guardian(s) of children diagnosed with T1DM, referred to as T1DM Caregiving Parent for purposes of this article. Synchronous, in-person, semi-structured interviews were conducted to collect qualitative data, and emergent heuristic content analysis was subsequently performed on transcripts. Eligible T1DM Caregiving Parents were identified from caregivers attending visits with children hospitalized or assessed in the Pediatric Neuroendocrinology Department of Shengjing Hospital, China Medical University in

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Shenyang from January 2018 to June 2019.

To be eligible for participation in study interview, T1DM Caregiving Parents were required to (1) be the parent and/or legal guardian of a child 14 years of age or younger with diagnosed T1DM, and (2) be a primary caregiver during at least 6 months of continuous care for child being treated for T1DM during this period[18] T1DM Caregiving Parents were considered ineligible to participate in interviews if (1) the child with T1DM also experienced other significant comorbidities or chronic diseases; (2) the child with T1DM was considered to require immediate medical care or treatment and the study could pose an undue burden on the patient or caregiver; (3) T1DM Caregiving Parent was unable to communicate fluently in the local language of the investigator (Mandarin Chinese).

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board (IRB) of Shengjing Hospital, China Medical University, Shenyang, China (Approval no. 2018PS362K). All participants provided written informed consent prior to participating in interviews.

Sampling Methods and Process

Purposive nonprobability sampling was used, in which eligible T1DM Caregiving Parents were approached for participation as they visited clinic. To ensure a representative sample, the heterogeneity of sample selection was expanded for T1DM Caregiving Parent age, marital status, education level, and T1DM child age and disease course. The study was discontinued when qualitative data reached saturation, which was expected to occur between 15 and 20 interviews, as previously described[19 20] When the number of interviews reached 20, the data in our research was saturated, and no new information was obtained, so sampling was terminated.

Data Collection

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An IRB-approved semi-structured interview outline was used to ensure consistency while performing interviews. The interview structure was based on the theory of individual and family self-management[21], and formulated through expert evaluation of the research purpose, population, and existent body of literature. The outline used in interviews is shown in **Table 1**. The planned duration of the interview was 45 to 60 minutes.

Upon arrival at the clinical site, the head nurse of the clinical unit familiar with the T1DM Caregiving Parent met the interviewee, led them to the interview site, and made introductions. Prior to the start of the interview, the interviewer explained the purpose, significance, methods, rights of the interviewee, and privacy protection measures. Written informed consent was then obtained before starting each interview.

The interview location was selected as audio visual classroom located in the Pediatric Neuroendocrinology Ward. This location was selected for the quiet environment, free of distractions. Interviews were conducted by the authors, who were provided with training on semi-structured interviews and use of neutral, objective, and non-leading language during the interview to maximize data integrity.

Data Transcription and Coding

Each interview was recorded using audio recording devices, and digitally transcribed asynchronously (with 48 hours after each interview) by the researchers. Transcripts were recorded in MS Word (Microsoft, USA), and verified by a second researcher. To ensure data integrity, interviewees were provided with a copy of their interview transcript and allowed to suggest corrections, which, if appropriate, were assessed and integrated by the researchers upon review of the original recording.

Heuristic coding was performed using emergent grounded theory methods[20] manually using transcripts imported into NVivo 11.0 (QSR International, USA) using

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manual code to summarize text data, and identify and refine themes. Coding was verified by a second researcher, the numbers were used to identify the interviewees in place of their real names, DM1-DM20. Emergent themes and subthemes were identified using a grounded theory approach.

Data Analysis and Reporting

Textual coding results in NVivo 11.0 were reported as counts and percentages (data not shown) and themes/sub-themes were presented descriptively using qualitative analysis methods. All analyses were performed in the local language of the interview conduct (Mandarin Chinese), and the data were analyzed and collected simultaneously. The theme of the interviews was extracted using content analysis methodology by way of three-grade coding. Final results were translated to English, and all translations were performed by the researchers to ensure integrity of translations.

Results

Participant Characteristics

Saturation was reached when 20 T1DM Caregiving Parents (N = 20) completed interviews. Interviewed T1DM Caregiving Parents included 7 fathers and 13 mothers (gender roles were self-identified by the interviewee), aged 30 to 53 years, with their children mean age of 10.6±2.45 years. Of these patients, 8 were caregivers of children with T1DM that were treated with insulin pumps, and 12 were caregivers of children with T1DM that were treated with subcutaneous injections. Socio-demographic information for T1DM Caregiving Parents completing interviews and demographic and clinical condition of their children are summarized in **Table 2**.

By analyzing the transcripts of interviews, five major emergent themes were observed

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consistently throughout the interview data: (1) persistent psychological stress; (2) family function changes; (3) challenges in daily management; (4) excessive economic burden; (5) lack of support system. All 13 minor subthemes within these 5 themes, are summarized in **Table 3**. The themes/sub-themes are further characterized below.

Theme of Persistent Psychological Stress

Persistent psychological stress was identified as prominent theme across interviews, with four key sub-themes emerging from coding:

(1) Catastrophic Emotional Experience

In acute period following diagnosis, parents often experienced emotions that can be described as catastrophic, including shock, fearfulness, frustration, hopelessness, sadness, and feelings that disaster is imminent.

Interviewee DM2: "When the doctor told me that my child was diabetic, I felt like [I was] struck by lightning and the sky was falling. My child's life is basically over."

(2) Emotional Distress Based in Negative Emotions

Negative emotions observed in T1DM Caregiver Parents primarily included continual worry, anxiety, sadness, stigma, annoyance, and guilt. Worry was embodied in anxiety and sadness, often with connections to the uncertainty of disease progression in their child. Some parents also experienced symptoms of worry and invasive thoughts about the potential for their children to be discriminated in the future because of their illness, leading some to even report hiding their child's illness in common social contexts. Further, parents reported feeling guilt linked to social isolation and dietary restrictions experienced by their child, etiology of illness (often linked to limited clinical understanding of T1DM), or feeling of being "at fault" for their child's condition.

Interviewee DM2: "It's still like a sword hanging over my head. I don't know when

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the complications will come. I live with fear every day."

Interviewee DM6: I don't want people around to know that my child has diabetes. Diabetes is an undead cancer. Thinking about it in another way, who wants his child to marry a diabetic in the future? You may only have to marry someone who also has diabetes. My child doesn't want her classmates to know that she is different from others."

Interviewee DM3: "My thoughts are that he is too young and suffers too much. He has to get injections and blood tests every day, and his fingers are pierced constantly. As a parent, I feel like a failure. I have not taken good care of my child and have been busy with work. I feel like I neglect taking care of him."

(3) Altered Sense of Self-Efficacy

T1DM Caregiver Parents also showed self-doubt owing to lack of experience in chronic disease care. In the most extreme cases, these feelings manifest as a severe lack of self-compassion, wherein parents expressed doubt in their ability to competently care for their child.

Interviewee DM6: "Taking care of [my daughter], it's not that I think I can or can't, but that I must be able to do. It's like a parent's obligation. If I can't, what else can she do? It's not something I can or can't do. It's something I must be able to do."

(4) Perceived Increased Responsibility for Parenting

T1DM Caregiver Parents reported perceiving a heavier burden of responsibility to manage their child's disease and remain hypervigilant, in particular for young children with T1DM not capable of self-managing. Parents perceive that, compared to children without T1DM, both parents and children bore additional responsibilities.

Interviewee DM19: "Now our child is too young to take care of herself. As parents, we are duty-bound, we have to be good supervisors. We supervise our child's diet,

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exercise, blood glucose testing and injections. Although we are not professionals, we will be dedicated to protecting our child's health. "

Altered Facility Function

Changes in family life included two prominent subthemes:

(1) Changes in Patterns of Family Life

Changes in routine patterns of daily living within the family unit were consistently reported by T1DM Caregiver Parents. These changes included changes in family activities designed to assist children in adapting to their life after T1DM diagnosis. On one hand, parents reported striving to retain normalcy for their children; however, the child's T1DM was also often reported to be disruptive to others, particularly other children, in the family unit. Parents also reported aiming to incorporate blood glucose measurement in routine daily living activities of the family unit, with mixed success.

Interviewee DM16: "It is inevitable that [when living with a child with T1DM] you can't be the same as other families. We have to consider our child's physical strength and whether [he] can eat regularly. Especially when faced with a table full of good food, it is uncomfortable for the child to see others eating."

Interviewee DM18: "Now we guide our child to think that measuring blood glucose and injecting insulin is a routine in life, just like showers before bed. We don't want our child to feel that injecting insulin before meals is a burden."

(2) Changes in Parental Role and Function

T1DM Caregiver Parents consistently reported that they perceived differences between their "normal" role and function compared with their prior lifestyle before their child's diagnosis. Specifically, T1DM Caregiver Parents expressed that their child's diagnosis affected their future career planning, life focus, and goals, and often resulting in a greater amount of time spent tending medical needs of their child.

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Interviewee DM5: "Now I rarely focus my energy on the company [I work for], just get off work as soon as possible. I used to leave early and return late to make money. Now I quit my job and found a new one that can make a living while taking care of my child. When she is on vacation, so am I."

In some cases significant housing and job/school changes are made to accommodate the child's T1DM care.

Interviewee DM14: "My family is in the countryside, but our child comes to a school in the city. Since our child has the disease, diabetes, and cannot live in school, I have to accompany him to study. My child and I rented a house near the school, which is convenient for me to take care of him, and we will return to the countryside during vacation, where his father works.

Challenges in Daily Management Theme

Challenges in daily management were consistency reported by T1DM Caregiver Parents, including:

(1) Technical Difficulties in Blood Glucose Management

T1DM Caregiver Parents reported technical difficulties in blood glucose management, including unsatisfactory or irregular blood glucose levels, primarily associated with dietary control, exercise compliance, untimely blood glucose monitoring, and insulin injection dosage adjustment. Parents expressed that lack of self-management, often owning to social and educational obligations, was often a key concern.

Interviewee DM3: "He is in the second grade of junior high school. There is a lot of tutoring outside school. He has to get up at 5:30 in the morning to study and finish school at 5:30 in the evening. If goes to the tutoring class, he returns at 8:30. There is no time to exercise. At school, his blood glucose control was poor [but] it is impossible to ask him to leave school to take measurements before and after meals."

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(2) Emotional Regulation and Managing Parent-Child Conflict

In addition to the regulation of T1DM Caregiver Parents' own emotions, interviewees also reported difficulty in assessing and managing their child's emotional and psychological needs.

Interviewee DM14: "[My daughter with T1DM] feels that if her classmates know she is sick and can't be cured, she will be inferior to others. Often it was lunch at noon, and she went to the toilet to get an injection, because she is afraid of being discriminated against by her classmates or something. Our child's self-esteem is strong, so she ran to the toilet for injections; at that time, if another child went to the toilet, she would be frightened, remove the needle and hurriedly put it away. She would not press and was still bleeding. As a parent, I feel distressed, but I don't know how to help the child to feel better."Interviewees consistently reported that parent-child conflict stemmed from inability to communicate effectively and perception of their children's poor compliance with disease management. As children age and their sense of autonomy increases, parents reported difficulty in transitioning to stages where their child exerts greater autonomy over their T1DM care and monitoring. In particular, interviewees reported resistance from their child, and perceptions that the child felt controlled by the parent's actions.

Interviewee DM20: "I understand that the child is also upset and there is no place to vent. I restrict her diet and control her blood glucose measurements. How can she not resist psychologically? I feel that I can't get into her heart, I don't know how to get along with her."

(3) Transition from Parental Management to Self-Management as the Child Ages

With changes in their child's growth and developmental stage, the roles and function

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of children and parents in T1DM management shifts. However, premature transfer of diabetes management tasks to children with T1DM is now considered a factor leading to poor blood glucose control. Many T1DM Caregiver Parents expressed uncertainty or frustration on transition timing.

Interviewee DM15: "In the first year, we helped her with her insulin injections, and then she did it by herself for the next two years. The blood glucose monitoring at night was not done, so the glucose control was not good. Such an old child is really difficult to manage, half-sensible but not sensible."

Excessive Financial Burden Theme

T1DM Caregiver Parents consistently reported the excessive financial burden of caring for a child with T1DM, including high cost of treatment. This burden was often cited as a factor for job and educational changes, affecting family member circumstances. Due to the long-term nature of treatment, medications and injection supplies are consumable items with sustained cost impact. Furthermore, caring for a young child with T1DM often requires care around the clock, with some parents reporting that one of the parents gave up employment, changed employment, or reduced hours to provide adequate care for their child, often decreasing household income and adding further financial stress to middle- and low-income families.

Interviewee DM2: "Using an insulin pump is a great economic pressure. It costs nearly 20,000 CNY [about 3000 USD] a year. One tube is normally more than 110 CNY [about 17 USD]. I will buy some during sales and let my friends buy some more from other channels. A tube can be used for three days. It costs nearly 20,000 CNY [about 3000 USD] a year.”

Lack of Social Support Systems Theme

The lack of support system primarily includes limited social activities and insufficient

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social support system, as described below:

(1) Limited Social Activities

At present, the family structure in China is dominated by a typical nuclear family, and children are generally a primary focus of the family unit. Once a child is diagnosed with T1DM, T1DM Caregiver Parents reported feeling disruption in the social activities of the family unit. In particular, mothers in the interview often left their employment, changed careers, or reduced hours to be able to care for their child with T1DM, thus narrowing their social circle to the immediate family members. This transition can result in social isolation and limit normal social activities of the parent.

Interviewee DM10: "Since my child had a ketosis coma, I have never dared to relax again. I have lost myself. Every day in the year, there are no more visits to relatives or friends."

(2) Insufficient Other Support Systems

Insufficient systems of social support were a common concern of T1DM Caregiver Parents, especially those of children reaching school age and assuming autonomy over their care during school hours.

Interviewee DM12: "Unlike other countries, our children do not have diabetes nurses in school. When the child is at school, every time the teacher calls, I am terrified, always scared that something bad will happen. If the child's blood glucose is low, does the teacher know how to handle it? Will it be delayed?"

Discussion

This study aimed to qualitatively examine perception of common challenges among parental caregivers of children with T1DM. Using Grounded Theory (GT), a method based in social science research [20-21], researchers examined and consolidated

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emergent themes from interview transcripts. In this study, parental caregivers of T1DM children consistently reported persistent psychological stress, changes in routine functions of the family unit, challenges in daily disease management for both the child and parental caregiver, financial strain, and disruption of social activities. Thus, this qualitative study and the following sections aim to provide actionable insights for both future research and patient support programs.

Reducing Persistent Psychological Strain in Parental Caregivers of Children with T1DM Experience

This study showed that parental caregivers of children with T1DM were particularly susceptible to psychological stress during the early stages after their child's first T1DM diagnosis. These stressors manifested as recollections of negative emotions leading to emotional distress, including shock, sadness, and anxiety. Further, repeat insulin injections and finger blood glucose monitoring in child posed not only technical challenges for non-medical professional caregivers, but also emotional distress in parental caregivers. Shortly after a child's diagnosis, many parental caregivers reported feelings of disbelief, resulting in catastrophic emotional disturbances linked to shock, fear, frustration, despair, and sadness. These findings are consistent with other quantitative psychological studies demonstrating posttraumatic stress disorder (PTSD) symptoms in caregivers[20 22-24]; however, the use of qualitative interview methods enables additional insights into the character of reflective perceptions of parental caregivers, and how such condition can be relieved. Our study suggests that the emotional effects of "invisibility" of the T1DM prior to diagnosis can trigger guilt and anxiety that exacerbate psychological stressors. Further, young age of the child and uncertainty of social impact can also increase psychological pressure on the caregiver, leading to anxiety and PTSD manifestations. In some cases,

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these stressors can lead to catastrophic emotional experiences occurred in the early stage of diagnosis and during a child's hospitalization, which is consistent with other research[25].

In particular, following the hospital discharge of a child with T1DM, parental caregivers in this study noted a variety of negative emotions, in particular poorly controlled worry, anxiety, sadness, stigma, annoyance, and guilt. During the course of our interviews, it was found that worry, anxiety, and sorrow were closely linked to uncertainty of disease progression. This observation is consistent with prior studies that have shown parental caregivers of children with T1DM experience a heightened level of disease uncertainty compared to caregivers of other chronic states, which can exert adverse effects on the health and psychological condition of the parental caregivers and the children they care for[26]. Thus, medical staff should pay particular attention to these potential effects in early stages of the disease progression.

Parental caregivers, in part due to their emotional bond with their child, are also affected emotionally by perceived stigma. Stigma refers to a kind of inner shame caused by illness that is viewed as a deficiency, which negatively affects patient psychology and can contribute to noncompliance or delay of critical treatment and monitoring in T1DM[27]. During the interviews conducted in this study, some parents of children with T1DM expressed that diabetes would affect their child's future employment, marriage, and social standing, in some cases going so far as to hide their child's condition to avoid perceived discrimination. Stigma affects caregivers by playing on their guilt, which may be exacerbated by "causing" pain to the child through blood tests and limiting activities or diet. Some parents also have limited scientific understanding of the illness, and perceive the disease to be a result of neglect in care that can further exacerbate feeling of guilt, anxiety, and depression.

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Parent's persistent emotional distress affects their own physical and mental health, thereby affecting management of blood glucose control in their children[28]. Thus, whether or not parental caregiver have let the stigma to influence their emotional state concerns medical staff, related to the treatment of children with T1DM.

As prior research has shown, the self-efficacy of parental caregivers in diabetes management is related to the effectiveness of blood glucose control[29]. In the interviews conducted during this study, parental caregivers emphasized expectations placed on the mother's role, and their increased sense of self-efficacy. Parents that perceived themselves as competent in the role of caregiver consistency experienced less emotional distress. Through analyzing interviews, this study found that the psychological burden of parents primarily derives from the following courses: (1) Pressure of blood glucose management in children, especially in diet management; (2) Children's physical and mental pain caused by insulin injections, blood glucose monitoring, and diet restrictions; (3) Mood changes in children due to illness; and (4) The impact of the disease on the children's future. These insights can be used to design integrated patient management programs that consider both parental caregiver emotional health and the medical condition of the T1DM child.

Supporting the Transition of Parents into an Evolving Caregiver Role

Becoming a caregiver of child with T1DM is disruptive not only to the parent(s), but also to the family unit. Furthermore, the emotional burden on parental caregivers is increased by an evolving need for autonomy over T1DM care as children age. For younger children with T1DM, parental caregivers will need to dedicate substantial time and financial resources to their child's daily care, such as regular blood glucose measurement, injecting insulin, monitoring their diet and physical activities, and handling emergent issues. Common challenges in daily management include difficulty in blood glucose management, emotional management, parent-child conflict, and the transition from parental management to self-management. While technology has improved T1DM care through the use of insulin pumps and continuous blood glucose monitoring, often young children may not have access to these technologies or compliance may not be possible[30]. These changes in activities of daily living in the family unit also impact relationship between parents and children, leading to conflict. Thus, additional care is needed in the community and clinical setting to support parents transitioning through the various stages of T1DM caregiver roles.

Parental caregivers of children with T1DM also face challenges in transitioning their role to manage their child increased autonomy with age. In this study it was apparent from interviews that, even at a young age, issues of the child's autonomy could affect the parent-child relationship and lead to family conflict. Previous studies have shown that families often experience conflicts in chronic disease care setting. In particular, children with T1DM and high levels of family conflict have been shown to have poorer blood glucose control and lower overall quality of life[31 32]. As young children grow into adolescence, these conflicts may become more common or escalate. Khandan (2018)[33] found that when children with T1DM reached the age of 8 to 11, their parents begin to transfer diabetes management responsibility to them, gradually transitioning from "parental responsibility" to "cooperative support." While parents have a high degree of control over their young child's medical care, they may require outside support from clinicians or the community in transitioning these responsibilities as their child enters adolescents. Appropriate mental health and community support may thus improve outcomes among these children and their caregivers and help to achieve an effective transition to self-management as these children enter adolescence.

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Improving Financial and Social Support Systems for Parental Caregivers of Children with T1DM in China

In this study parental caregivers of children with T1DM consistently reported a strain on household finances related to their child's care and disposable supplies, and a lack of social support. In the majority of cases, discussed in the present study, expenses were covered by insurance only during hospital stay, but after discharge the expenses were paid by parents/guardians. Insulin medication was also partly covered by health insurance, but the reimbursement rate varied depending on the type of health insurance (up to 90%). Similar to the results of other studies[34], medications and disposable devices used for long-term treatment place a substantial and ongoing burden on these families, often affecting housing, employment, and economic opportunities for middle- and low-income families. Financial burden not only affects the physical and mental health of parental caregivers, but also limits or delay selection of treatment options that can influence the T1DM child's long-term prognosis.

Furthermore, the lack of social support and relative social isolation of caregivers, particularly those that reduced hours or left jobs to act as primary caregivers (most common among mothers), was consistently reported in this study. The lack of support systems was apparent from limited family social activities, which often negatively impacted the parental caregiver's emotional state. Compared to other developed regions, China currently has a lack of diabetes nurses in kindergartens and primary or secondary schools. Thus, preschool and school-age children have to assume the responsibility of diabetes self-management during school hours. In addition many parents in this study reported that blood sugar control was not ideal during school hours, because of self-esteem issues or poor self-control. Therefore, we propose that we should, as a healthcare system, selectively learn from the successful experience of

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other countries[35] and gradually implement training for school personnel and other personnel who contact with diabetic children, to improve the social support system for children with diabetes.

Notably, this research is limited by the interpretation of the reviewers and coders. In particular, all interviewees and researchers were from a single hospital, which limits the generalizability of the findings to a broader population. However, these insights provide greater depth than mere quantitative characterizations, and may aid in improving both psychological and physical outcomes of children with T1DM and their parental caregivers.

Conclusions

This qualitative study employs grounded theory methods to examine the emergent themes through a series of interviews that address the perceptions of parental caregivers of children with T1DM, giving voice to the common challenges faced by parental caregivers as their young children are first diagnosed with T1DM and slowly gain autonomy for their own chronic disease management with age. This research demonstrates common themes of persistent psychological stress, difficulty managing changes in family function, challenges in daily disease management, challenges of excessive financial burden, and the impact of a lack of social support for parental caregivers. By characterizing these common perceptions and experiences, we can better prepare health care providers to support both the T1DM child and parental caregivers as they adapt to medical management of T1DM at different stages, thereby improving their self-management capabilities.

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List of abbreviations

T1DM	Type 1 Diabetes Mellitus
QoL	Quality of life
GT	Grounded Theory
PTSD	posttraumatic stress disorder
IRB	Institutional Review Board

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Declarations

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Ethics approval and consent to participate: This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board (IRB) of Shengjing Hospital, China Medical University, Shenyang, China (Approval no. 2018PS362K). All participants provided written informed consent prior to participating in interviews.

Consent for publication: Not applicable

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Table 1 Semi-Structured Interview Outline for Parents of Children Aged ≤14 with Type 1 Diabetes Mellitus (T1DM Caregiving Parents)

Question #	Description
1	Could you please talk about the situation when your child was first diagnosed with type 1 diabetes and your reaction at that time?
2	Could you please describe a day of caring for a child with type 1 diabetes?
3	Since your child was diagnosed with diabetes, what has been your biggest concern, or what is the most difficult issue you have had to deal with?
4	How do you help your child manage his/her diet?
5	How do you help your child manage his/her medication?
6	How do you help your child manage his/her activities or exercise?
7	How do you help your child manage his/her emotions?
8	How do you manage your own life while taking care of your child?
9	As a caregiver, what are your needs in caring for the child?
10	Do you think you are qualified for the role of caring for a child with type 1 diabetes?

Note: This outline has been translated from the original Mandarin Chinese version. All interviews were conducted in the local language of the investigator (Mandaring Chinese).

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Table 2 Characteristics of Parental Caregivers of T1DM Children (T1DM Caregiver Parents) Interviewed

Characteristic	**Interviewee** **(n = 20)**
Children	
Age (years), mean±SD	10.6±2.45
Onset age of T1DM, mean±SD	7.2±2.4
Insulin regimen, n (%)	
Insulin pump use	8 (40%)
Daily injections	12 (60%)
Gender, n (%)	
Male	7 (35%)
Female	13 (65%)
Parents	
Age(year), mean±SD	39.45±6.21
Gender, n (%)	
Male (self-identify as Father)	8(40%)
Female (self-identify as Mother)	12(60%)
Current employment status, n (%)	
Full-time	8 (40%)
Part-time	6 (30%)
Not working	6 (30%)
Highest education level, n (%)	
Junior high (middle) school or some high school	6 (30%)
High school diploma	6 (30%)

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Technical school (2-year degree or equivalent)	3 (15%)
Bachelor's degree (4-year degree or equivalent)	5 (25%)
Monthly Income (CNY/USD), n (%)	
< 3077/500	5 (25%)
3077-11428/500-1700	9 (45%)
>11428/1700	6 (30%)

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Table 3 Themes and Sub-themes Emerging from Interviews of Parental Caregivers of T1DM Children (T1DM Caregiver Parents)

Themes	**Subthemes**
Persistent psychological stress	(1) catastrophic emotional experience (2) emotional distress based in negative emotions (3) altered sense of self-efficacy (4) perceived increased responsibility for parenting
Family function changes	(1) changes in patterns of family life (2) changes in parental roles and functions
Challenges in daily management	(1) technical difficulties managing blood glucose (2) difficulties in emotional regulation and managing parent-child conflict (3) transition from parental management to self-management as the child ages
Excessive financial burden	(1) burden of disease treatment (2) changes in economic sources
Lack of social support system	(1) limited social activities (2) insufficient other support systems

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Table Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description	Page
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	24
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	01,24
3.	Occupation	What was their occupation at the time of the study?	24
4.	Gender	Was the researcher male or female?	24
5.	Experience and training	What experience or training did the researcher have?	08
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	07
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.*g. personal goals, reasons for doing the research*	08
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*	08
Domain 2: study design			

No	Item	Guide questions/description	Page
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	09
Participant selection			
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*	07
11.	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*	08
12.	Sample size	How many participants were in the study?	09
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	07
Setting			
14.	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*	08
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	08
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*	10, Table 2
Data collection			
17.	Interview guide	Were questions, prompts, guides	08

No	Item	Guide questions/description	Page
		provided by the authors? Was it pilot tested?	
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	n/a
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	09
20.	Field notes	Were field notes made during and/or after the interview or focus group?	09
21.	Duration	What was the duration of the interviews or focus group?	08
22.	Data saturation	Was data saturation discussed?	07
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	09
Domain 3: analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	09
25.	Description of the coding tree	Did authors provide a description of the coding tree?	09
26.	Derivation of themes	Were themes identified in advance or derived from the data?	09
27.	Software	What software, if applicable, was used to manage the data?	09
28.	Participant checking	Did participants provide feedback on the findings?	09

No	Item	Guide questions/description	Page
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number*	10-16
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	17
31.	Clarity of major themes	Were major themes clearly presented in the findings?	10,17, Table 3
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor them	10, Table 3

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