

Cite as: Ping YR, Jia ZM, Huang JR, Liu FF, Liu K, Lei J, Wang MM, Wang XG. Progress and prospects for application of continuous glucose monitoring in patients with type 2 diabetes mellitus [J]. Chin J Clin Res, 2024, 37(7):1008-1012.

DOI: 10.13429/j.cnki.cjcr.2024.07.005

Progress and prospects for application of continuous glucose monitoring in patients with type 2 diabetes mellitus

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Abstract: There is a large number of patients with type 2 diabetes mellitus (T2DM) in China, with great heterogeneity among individuals, and the glycemic control rate is low. Continuous glucose monitoring (CGM) can directly reflect the fluctuation of blood glucose of patients, which is beneficial to both doctors and patients in finding and correcting abnormal blood glucose in time, promoting patients' behavior change, and improving their self-management ability. This article will briefly introduce CGM, elaborate the effects and obstacles of CGM in patients with T2DM, and put forward coping strategies, so as to provide a reference for promoting the CGM program. This article will briefly introduce CGM, elaborate on the effects and obstacles of CGM in patients with T2DM, and put forward coping strategies, as to provide a reference for promoting the widespread application of CGM in patients with T2DM.

Keywords: Continuous glucose monitoring; Blood glucose management; Type 2 diabetes mellitus; Self management; Quality of life; Sleep; Psychological condition

Fund program: Henan Province Medical Science and Technology Research Plan Joint Construction Project (LHGJ20210596)

Diabetes mellitus has a high prevalence, with type 2 diabetes mellitus (T2DM) accounting for more than 90% of the total number of diabetes patients[1]. Glucose monitoring not only helps diabetic patients to understand the characteristics of their own blood glucose fluctuation and blood glucose control, but also is the cornerstone of treatment decision-making and adjustment of treatment program for T2DM patients. Research shows that blood glucose levels in half of adult diabetic patients in China still abnormal[2]. Large fluctuations in blood glucose will increase the risk of diabetic complications and all-cause mortality, affecting the quality of life of patients[3]. There is an urgent need to improve the glycemic control rate of T2DM patients. Currently, inpatient and home blood glucose monitoring of T2DM patients are still based on regular glucose monitoring such as fingertip blood-free reliable glucose monitoring and hemoglobin A1c (HbA1c) test. Continuous glucose monitoring (CGM) is a new technology that continuously monitors the glucose concentration in interstitial fluid and sends the glucose data to a designated receiver for physicians and patients to understand the blood glucose levels and fluctuation of blood glucose[4]. Compared with self-monitoring of blood glucose and HbA1c test, CGM can assess the patient's blood glucose status more comprehensively and visually. In recent years, CGM has been gradually applied to patients with T2DM, with good results. This study reviews the current status of CGM application in T2DM patients and discusses the direction of future development, so as to provide a reference for promoting the application of CGM in T2DM patients and strengthening the glycemic management of T2DM patients.

1 CGM Overview

1.1 Types of CGM

In recent years, with the continuous improvement of CGM technology, all kinds of CGM products have emerged and have their characteristics. Overseas, Medtronic, Dekang, and Senseonics manufacturers of CGM mainly occupy a dominant position in the market, the speed of product replacement, of which Dekang has developed the seventh generation of CGM products. Domestic research and development of CGM products have accelerated the process of CGM products in the market circulation of CGM, mainly including Microtek Dynamic, Medtronic, Abbott, Silicon-based, etc[5]. New CGM technology ensures high accuracy in the realization of non-invasive blood glucose monitoring. In addition, it automatically measures blood glucose every 3 to 5 minutes, provides high and low glucose alarms, generates blood glucose maps, and can be used continuously for 180 days. These advantages make up for the shortcomings of traditional blood glucose monitoring on a technical level and cater to different patient demands and research needs. According to the usage characteristics, the types of CGM include real-time CGM, retrospective CGM, and scanning CGM. Patients can obtain immediate blood glucose information and understand their blood glucose trends when using real-time CGM. Retrospective CGM, also known as blind CGM, means that patients are not able to see the change in their blood glucose during the wearing period, and the blood glucose data need to be downloaded at the end of the wearing period. When using

scanning CGM, patients can scan the sensor to obtain the current glucose data according to their needs[6]. Three types of CGM products have different advantages and disadvantages, and the performance of new-generation products is not necessarily superior to the previous generation. Healthcare professionals should consider the needs of patients and recommend appropriate CGM products for diabetic patients.

1.2 Current status of CGM development

In 1999, the U.S. Food and Drug Administration (FDA) approved the clinical application of CGM to measure blood glucose in diabetic patients. Subsequently, foreign scholars found that glucose was closely related to HbA1c, diabetic retinopathy, diabetic lower limb vasculopathy, cardiovascular disease, and cervical intima-media thickness during time in range (TIR). When CGM is applied to type 1 diabetes mellitus (T1DM), gestational diabetes mellitus, and perioperative blood glucose management, the incidence of hypoglycemia in patients is reduced, pregnancy outcomes are improved, and the waiting time for preoperative surgery is shortened[7-9].

Domestic attention to CGM and CGM product development started late. In recent years, CGM research has focused on analyzing the relationship between CGM indicators and diabetic complications, analyzing patients' blood glucose fluctuations with the help of CGM, and observing the effects of CGM on T1DM and gestational diabetes patients. Domestic CGM will only be approved for marketing in 2021. However, its price is relatively low, and its accuracy is high. It is believed that with the people's understanding of CGM, the continuous optimization of domestic CGM technology, and increasing patients' demands, domestic CGM will gradually increase. It is believed that with people's understanding of CGM, continuous optimization of domestic CGM technology, and increased patient demand, domestic CGM will occupy progressively the domestic market. It is worth noting that scholars at home and abroad have just applied CGM to T2DM patients in recent years.

2 Applications of CGM in T2DM

2.1 Improvement of blood glucose levels in T2DM patients

Numerous studies have found that CGM can help patients accurately estimate average blood glucose and reveal blood glucose variability that cannot be detected by self-monitoring of blood glucose (SMBG) [10-12]. A meta-analysis showed that CGM reduces HbA1c levels and shortens the time to hypoglycemia[11]. Cox *et al.*[12] found that in addition to a substantial reduction in HbA1c, the area under the curve of hyperglycemia was reduced in the patients in the CGM group, and patients also did not experience hypoglycemia. CGM also

improves blood glucose in T2DM patients on other treatment regimens. In a multicenter, randomized, parallel-group trial, T2DM patients on basal insulin therapy with CGM after 8 months showed significant improvements in TIR and time above the target range (TAR) [13]. Therefore, using CGM in the care of T2DM patients can help T2DM patients with glycemic management and achieve smooth glycemic control.

2.2 Influence of self-management behaviors in T2DM patients

Self-monitoring is a driver of behavioral change, and CGM can provide immediate feedback on the effects of diet, exercise, and medications to help patients change their self-management behaviors. A short-term and small-sample study conducted by Taylor *et al.*[13] enrolled 20 patients with overweight or obesity with T2DM into either a real-time CGM group or a blinded CGM group, and both groups were given a low-carbohydrate lifestyle intervention and found that patients in the real-time CGM group had improved their glucose monitoring behavior after 6 weeks. A study in which 41 patients with adolescent-onset T2DM wore a CGM for 10 days showed an increase in insulin use based on an increase in patients' glucose-monitoring behaviors and an overall improvement in diabetes management[14]. A combined intervention of "CGM+online peer-support community" by Litchman *et al.*[15] was administered to 26 Spanish patients with T2DM who did not use insulin for 12 weeks; the patients were given a "CGM+online peer-support community," the patients reported that the CGM supported them in adjusting their medication use and sleep schedule and in improving their ability to cope with stress. Therefore, CGM can be used as a motivational device, which is expected to be a new approach to glycemic management in T2DM patients and to encourage T2DM patients to change their poor lifestyles, master effective self-management methods, and improve their self-management ability. However, the intervention time of the above study is short, the sample size is small, and the intervention effect needs to be further verified.

2.3 Effects of CGM on quality of life in patients with T2DM

Some studies have applied CGM to patients with T2DM to observe changes in sociological indicators, mainly regarding quality of life.[16-18]. Beck *et al.*[16] conducted a multicenter, large-sample, randomized clinical trial by selecting 158 adult patients with T2DM who were injected with insulin several times a day. Patients in the intervention group wore CGMs, patients in the control group underwent routine care, and the follow-up was 24 weeks. After 24 weeks, it was found that patients who used CGM almost daily had a decrease in HbA1c. However, no difference in quality of life was found between the two groups. In contrast to Beck's

findings, a cross-sectional survey by Volčanšek *et al.*[17] of 25 elderly diabetic patients who received multiple daily injections showed a high level of patient satisfaction with the use of CGM, considering that half of the patients in the study were T1DM patients, causing the difference in the results of the two studies. In addition, another study recruited 122 T2DM patients who were not using mealtime insulin to provide them with CGM and related training. After 12 weeks, it was found that patients had reduced diabetes distress and improved quality of life based on patient-reported outcomes[18]. Therefore, CGM for T2DM patients can improve their quality of life and minimize disease-related distress. In reality, T2DM patients taking oral hypoglycemic agents account for the majority of the diabetes population. The effect of CGM use on the quality of life in this group of patients has not been reported in China, so it is recommended that the focus on the quality of life of T2DM patients with CGM should be strengthened in the future and that relevant studies should be conducted to expand the role of CGM in diabetes care beyond T1DM and T2DM patients treated with insulin.

2.4 Effect of CGM on sleep in T2DM patients

There is a strong correlation between sleep and blood glucose in T2DM patients[19]. However, the current studies on the relationship between sleep and blood glucose in T2DM patients are all observational studies. The study on sleep and blood glucose in T2DM patients found that the relationship between sleep duration and HbA1c was in the shape of a "U," and the HbA1c of patients with a shorter or longer sleep duration of more than 7-8 hours per night was worse[20]. However, the sleep in the above study was based on patients' self-report, which may not be consistent with the actual situation. A community-based observational study in Nanjing, Jiangsu Province, China, using activity loggers and CGMs to objectively record patients' sleep and wakefulness and blood glucose levels, also found that nighttime sleep duration was directly related to blood glucose variability and that longer nighttime sleep duration had a beneficial effect on insulin sensitivity, reduced energy intake, lowered the risk of postprandial hyperglycemia, and reduced daytime blood glucose variability[21]. Sleep is an important and modifiable factor in patients with T2DM, and prevention of sleep problems may become a priority in the future management of T2DM. Recently, a randomized controlled study on optimizing sleep to improve glycemic control in adults with T1DM has been published. The researchers proposed assigning 120 patients with T1DM to either the sleep optimization intervention group or the lifestyle control group and objectively recording patients' glycemic and sleep outcomes after 12 weeks of intervention using CGMs, activity loggers, etc.[22]. In the future, a combination of subjective and objective tools should also be used to monitor the sleep duration, number of awakenings, and sleep efficiency of T2DM patients to explore further whether measures to optimize the sleep of

T2DM patients can improve their glycemic control and other related health outcomes.

2.5 Effects of CGM on the psychology of T2DM patients

There is growing evidence of a strong correlation between mental health status and blood glucose. However, these correlation research results could not determine the causal relationship between the blood glucose results shown by CGM and the positive or negative emotions of T2DM patients. Overseas studies have pointed out that CGM can improve anxiety and depression in T1DM patients[23] and reduce the fear of hypoglycemia and diabetes distress[24]. For T2DM patients, Wagner *et al.*[25] showed that positive mood affects the time in the target glucose range and the standard deviation of glucose levels. In addition, another study found a strong association between mood and glucose variability[26]. The study by Xu *et al.*[27] confirmed that CGM combined with psychological counseling can help control blood glucose, improve mood, and improve the quality of life of hospitalized T2DM patients. However, this combined intervention failed to elucidate the direct effect of CGM on the health outcomes of T2DM patients. Future interventional studies may also focus on exploring the effects of CGM on the mental health of T2DM patients with different treatment regimens, such as anxiety, depression, and fear of hypoglycemia.

2.6 Effects of CGM on the economy of T2DM patients

Limited research has been conducted to analyze the cost-effectiveness of CGM in T2DM. CGM use reduces the risk of complications such as diabetic cardiovascular disease, diabetic foot, and patient mortality[28]. Particularly for patients with T2DM who are not using mealtime insulin and are in primary care, the use of CGMs is more cost-effective, reducing the number of patient visits and the cost of care, and improving the utilization of healthcare resources[29].

3 Obstacles in the CGM application for T2DM

Compared with T1DM patients, the proportion of T2DM patients using CGM for glucose monitoring is lower. Domestic and international guidelines also only recommend the use of CGM for monitoring glycemic changes in T2DM patients who receive intensive insulin therapy or have large fluctuations in blood glucose. The lagging effect of CGM and the economic level of patients are important factors that hinder the use of CGM in T2DM patients[6].

3.1 Lag of CGM

CGM sensors have been factory-calibrated to improve accuracy. However, scholars have found that,

except for the type of CGM and wearing position, exercise-induced physiological lag time is still a critical interfering factor in CGM accuracy, which hinders its popularization and application in diabetic patients. The rapid changes in blood glucose concentration during exercise and the increase in the glucose concentration gradient between the interstitial fluid and the blood lead to the inability of CGM to truly reflect the level of blood glucose changes during exercise, which indirectly affects the adjustment of insulin dosage and dietary decisions of the patients[30], which reminds us that it is important to understand the physiological lag time caused by exercise as accurately as possible. Zaharieva *et al.*[31] used a newer real-time continuous glucose monitoring technique to allow diabetic patients to engage diabetic patients in 60 minutes of aerobic exercise and found that CGM glucose values lagged (12 ± 11) minutes during aerobic exercise compared to SMBG. Considering the effect of varying exercise intensities on CGM accuracy, Da *et al.* showed that CGM accuracy was better during high-intensity intermittent exercise than moderate-intensity aerobic exercise, which is in the clinically acceptable range. In addition, Dexcom's CGM technology was updated again in 2020, and Guillot *et al.*[33] found that the type of exercise did not affect DexcomG6 CGM accuracy when they studied the accuracy of the DexcomG6 glucose sensor during aerobic, resistance, and intermittent exercise. The advantages of CGM for the management of patients with diabetes are becoming increasingly prominent, with CGM glucose values during aerobic exercise. During aerobic exercise, CGM blood glucose values have a long lag time; high-intensity exercise shortens the lag time of CGM blood glucose, and the type of exercise does not affect the accuracy of CGM. Domestic CGM technology is becoming increasingly mature, and it has not yet been reported how the accuracy of CGM developed by Silicon Power, Microtek, and other vendors compares with that of SMBG and venous blood during exercise.

3.2 High economic burden on patients

A survey in the United States found that direct medical expenditures for diabetes amount to \$237 billion annually[36]. Diabetic patients spend US\$2,500-6,000 per year on CGM. In developed countries, health insurance reimbursement only covers T1DM and T2DM patients treated with insulin, leaving other diabetic patients with a more significant financial burden[37]. Although no domestic scholars report the cost of CGM in Chinese diabetic patients, the number of diabetic patients ranked first in the world, the per capita income is far less than that of developed countries, coupled with incomplete health insurance policy, which limits the accessibility of CGM for T2DM patients in China.

3.3 Other barriers

Similar to the feelings of T1DM patients, CGM

wear-related pain, body image issues, alarm fatigue, information overload, skin irritation, and lack of knowledge about CGMs are also barriers to CGM use in T2DM patients[38]. A retrospective study by Tilden *et al.*[39] analyzed the 3-year rate of CGM use in 2008 diabetic patients and found that CGM use rates were 49% lower in patients residing in urban areas, compared to patients residing in remote rural towns. A retrospective study by Tilden *et al.*[40] analyzed 3-year CGM use among 2,008 patients with diabetes and found that the use of CGM was 49% lower among patients living in remote rural towns compared to those living in cities, and that geographic location also influences CGM use among patients with diabetes. In addition, it has been found that barriers to CGM use among adolescents with T2DM are different from those among patients in other age groups. The perceived burden and benefits of CGM use may vary throughout the lifespan of patients with T2DM, and attention needs to be paid to the young, middle-aged, and elderly populations as well.

4 Future perspectives

4.1 Further strengthen CGM education and improve the acceptability of T2DM patients

CGM can be used as an auxiliary educational tool to improve the effect of glycemic control in T2DM patients. The four primary functions of CGM include the formation of glycemic fluctuation curves and ambulatory glucose profiles, indicative trend arrows, the issuance of alerts, and the realization of remote sharing. While healthcare professionals strengthen CGM theory and operation, health education for patients should also cover the above content to help patients correctly analyze and identify the reasons for poor glycemic management, improve the utilization and response of patients to alerts, and improve the skills of diabetic patients to navigate CGM technology. Oser *et al.*[39] conducted a 6-week CGM education for 17 newly diagnosed adult T2DM patients, including distributing CGM instruction manuals, recording diaries, etc. At 3-month follow-up, patients' diabetic and depressive symptoms were significantly reduced, and 67% of patients achieved diabetes remission. Therefore, healthcare professionals should instruct patients to record daily events such as diet, exercise, and medication timely and accurately. By utilizing the CGM feedback function, they should also educate patients on how daily life events affect blood glucose. At the same time, patients should strengthen their connection with healthcare professionals to reinforce the effects of CGM health education, enhance the confidence to change their behavior, and improve the acceptability of CGM[10].

4.2 Improve CGM performance and CGM-wearing compliance in T2DM patients

CGM is increasingly used as a minimally invasive wearable device[40], but the CGM-wearing experience

hinders CGM-wearing compliance in diabetic patients. The first issue is CGM accuracy, which is affected by differences in blood and subcutaneous tissue glucose concentrations, lag time in sensor response, and blood glucose test strips used for calibration. Researchers are trying to solve this issue using advanced techniques such as metabolic thermal conformation and polynomial mapping. Healthcare professionals should advise patients to use glucose meters and test strips that are compatible with the CGM brand to minimize CGM's inaccuracy until this issue is solved[41-42]. Secondly is the problem of wearing pain. With the continuing progress of flexible CGM technology and the development of soft micro-needle glucose monitoring technology, and non-invasive skin patch glucose monitoring sensors, the patient's foreign body sensation and skin irritation can be minimized[43]. Finally, the appearance of CGM also affects patient compliance. In the next few years, nanotechnology is expected to greatly promote the miniaturization of CGM sensors and improve the CGM-wearing experience. CGM technology has been developed for over two decades, and it is believed that soon, CGM will achieve leapfrog development, benefit more diabetic patients, and assist patients in blood glucose management.

4.3 Short-term or intermittent use of CGM can reinforce behavioral change in T2DM patients

Long-term use of CGM can increase the financial burden of patients, and some studies have shown that short-term or intermittent use of CGM in patients with T2DM can be of more significant benefit[14]. A prospective, single-component trial enrolling 41 adolescents with T2DM who wore a CGM for 10 days found an increase in blood glucose monitoring and an overall improvement in diabetes management[14]. In addition, using a CGM every 2 to 3 months or at a fixed frequency when starting treatment and reinforcing lifestyle changes in patients with T2DM is also very useful and can be cost-effective [44]. A multicenter, randomized, controlled study from 8 countries in North America also showed that wearing a CGM once a month for 3 months in patients with T2DM who were taking multiple medications could have a modest glycemic benefit[45]. Short-term or intermittent use of CGMs in patients with T2DM may also be of high value. Clinical exploration of the optimal cut-off point for wearing CGM in T2DM patients will facilitate glycemic management while reducing the financial burden on patients.

5 Conclusion

CGM improves glycemia, self-management behaviors, and quality of life in T2DM patients on different treatment regimens and affects patients' slumber and psychological status. However, there are still many obstacles to the application of CGM in T2DM patients. More studies are still needed in the future to

deeply explore the effects of CGM health education, optimize CGM performance, and adopt short-term or intermittent use of CGM in different life cycles of patients with T2DM to provide an evidence-based reference to promote the application of CGM in patients with T2DM, and to facilitate the management of glycemia in patients with T2DM in China.

Conflict of interest None

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Submission received: 2023-12-27 Revised: 2024-03-21

持续葡萄糖监测在2型糖尿病患者中的应用进展及前景

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摘要: 中国2型糖尿病患者人数众多,个体间异质性较大,血糖管理达标率低。持续葡萄糖监测(CGM)能够直观反映患者血糖波动情况,有利于医患双方及时发现并纠正血糖异常,促进患者自身行为改变,提高自我管理能力和自我管理能力。本文简要介绍CGM,阐述2型糖尿病患者应用CGM的效果、障碍因素,并提出应对策略,旨在为推进2型糖尿病患者广泛应用CGM提供参考。

关键词: 持续葡萄糖监测; 血糖管理; 2型糖尿病; 自我管理; 生活质量; 睡眠; 心理状况

中图分类号: R587.1 **文献标识码:** A **文章编号:** 1674-8182(2024)07-1008-05

Progress and prospects for application of continuous glucose monitoring in patients with type 2 diabetes mellitus

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Abstract: There is a large number of patients with type 2 diabetes mellitus (T2DM) in China, with great heterogeneity among individuals, and the glycemic control rate is low. Continuous glucose monitoring (CGM) can directly reflect the fluctuation of patient's blood glucose, which is beneficial to both doctors and patients in finding and correcting abnormal blood glucose in time, promoting patients' behavior change, and improving their self-management ability. This article will briefly introduce CGM, elaborate on the effects and obstacles of CGM in patients with T2DM, and put forward coping strategies, so as to provide a reference for promoting the widespread application of CGM in patients with T2DM.

Keywords: Continuous glucose monitoring; Blood glucose management; Type 2 diabetes mellitus; Self management; Quality of life; Sleep; Psychological condition

Fund program: Henan Province Medical Science and Technology Research Plan Joint Construction Project (LHGJ20210596)

糖尿病患病率高,其中2型糖尿病(type 2 diabetes mellitus, T2DM)患者占糖尿病患者总数的90%以上^[1]。血糖监测不仅有助于糖尿病患者了解自身血糖波动特点和血糖控制情况,也是T2DM患者治疗决策及治疗方案调整的基石。研究显示,我国仍有半数成年糖尿病患者血糖不达标^[2]。较大的血糖波动将增加患者糖尿病并发症发生风险及全因死亡率,影响患者生活质量^[3]。因而临床亟需提高T2DM患者血糖达标率。目前T2DM患者住院及居家血糖监测仍以指尖血糖监测、糖化血红蛋白(hemoglobin A1c, HbA1c)测定等定时血糖监测方式为主。持续葡萄糖监测(continuous glucose monitoring, CGM)是一项创新技术,可持续监测皮下组织间液葡萄糖浓度,并将血糖数据发送至指定接收器,以供医患双方了解血糖水平及血糖波动情况^[4]。与自我血糖监测和HbA1c测

定相比,CGM可更加全面性、直观化地评估患者血糖状态。近年来CGM逐步在T2DM患者中得到应用,取得良好成效。本文就CGM在T2DM患者中的应用现状进行综述,并浅谈未来发展方向,为推进T2DM患者应用CGM,加强T2DM患者血糖管理提供借鉴。

1 CGM概述

1.1 CGM种类 近年来随着CGM技术不断完善,各类CGM产品层出不穷且各具特色。国外主要以美敦力、德康、Senseonics厂家生产的CGM在市场上占据主导地位,产品更新换代速度快,其中德康公司已研发出第7代CGM产品。国内CGM产品的研究也在加速进程,市面上流通的CGM主要包括微泰动态、美敦力、雅培、硅基等九大类^[5]。CGM新技术

DOI: 10.13429/j.cnki.cjcr.2024.07.005

基金项目: 河南省医学科技攻关计划联合共建项目(LHGJ20210596)

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出版日期: 2024-07-20



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在实现无创血糖监测的同时还保证较高的准确性。此外,CGM每3~5分钟自动测量1次血糖,提供高低血糖报警,生成血糖图谱,可连续使用180d等,这些优势不仅从技术层面弥补了传统血糖监测的不足,同时也迎合不同患者需求与研究需要。根据使用特点,CGM类型包括实时CGM、回顾式CGM和扫描式CGM。使用实时CGM时,患者可获得即刻血糖信息,了解自身血糖变化趋势;回顾式CGM又称盲法CGM,佩戴期间患者无法知晓其血糖变化,血糖数据需在佩戴结束后下载才可获得;患者扫描式CGM时允许患者根据自身需求扫描传感器即可读取当下血糖值^[6]。各类CGM产品各有其优缺点,新一代产品性能并不一定优于前一代,医护人员应考虑患者需求,为糖尿病患者推荐合适的CGM产品。

1.2 CGM发展现状 1999年美国食品及药品管理局(FDA)批准CGM临床应用于测量糖尿病患者血糖。其后相关学者通过CGM发现葡萄糖目标范围内时间(time in range, TIR)与HbA1c、糖尿病视网膜病变、糖尿病下肢血管病变、心血管疾病、颈动脉内膜厚度等密切相关^[7],将CGM应用于1型糖尿病(T1DM)、妊娠期糖尿病、围手术期血糖管理,患者低血糖发生率减少,妊娠结局改善,术前等待时间缩短^[8-9]。国内对CGM的关注以及CGM产品研发起步均较晚。近年来CGM研究集中于分析CGM指标与糖尿病并发症的关系,借助CGM分析患者血糖波动,观察CGM对T1DM及妊娠糖尿病患者的影响。国产CGM更是在2021年才获批上市,然而其售价相对较低,且准确性高,相信随着人们对CGM的了解,国产CGM技术不断优化以及患者需求增加,国产CGM将逐步占据国内市场。值得注意的是,国内外学者近年来才将CGM应用在T2DM患者。

2 CGM在T2DM中的应用效果

2.1 CGM可改善T2DM患者血糖水平 大量研究发现,CGM不仅可以帮助患者准确估计平均血糖,还可揭示自我血糖监测(self-monitoring of blood glucose, SMBG)无法发现的血糖变异性^[10-12]。一项荟萃分析表明,CGM不仅可以降低T2DM患者的HbA1c水平,还可缩短患者低血糖时间^[10]。Cox等^[11]发现在未用胰岛素的T2DM患者中,使用CGM组患者除HbA1c大幅度降低外,高血糖曲线下面积减小,患者也未发生低血糖。CGM还可改善其他治疗方案的T2DM患者血糖。在一项多中心、随机、平行组的试验中,接受基础胰岛素治疗的T2DM患者使用CGM8个月时TIR、高于目标范围内时间(time above range, TAR)均显著改善^[12]。因此,CGM用于T2DM患者护理中,可以帮助患者进行血糖管理,实现平稳控糖等。

2.2 CGM可改变T2DM患者自我管理行为 自我监测是行为改变的驱动力,CGM可提供饮食、运动、药物效果的即刻反馈,帮助患者改变自我管理行为。在Taylor等^[13]进行的一项短期小样本研究中,同时给予实时CGM组和盲法CGM组T2DM患者低碳水化合物的生活方式干预,发现实时CGM组患者在第6周时,血糖监测行为已有所改善。另一研究在41

名青少年发病的T2DM患者佩戴CGM10d后,结果显示患者血糖监测行为增加的基础上,胰岛素使用增加,糖尿病管理总体改善^[14]。Litchman等^[15]对未用胰岛素的26名西班牙T2DM患者进行为期12周的“CGM+在线同伴支持社区”的联合干预时,患者也表示CGM可支持他们调整药物使用及睡眠时间,提高应对压力能力。因此,CGM可作为激励装置,有望成为T2DM患者血糖管理的新方法,促进T2DM患者改变不良生活方式,掌握有效自我管理方法,提高自我管理能力。然而上述研究均干预时间较短,样本量小,干预效果有待进一步验证。

2.3 CGM对T2DM患者生活质量的影响 部分研究将CGM应用于T2DM患者观察以生活质量等为主的社会学指标的改变^[16-18]。Beck等^[16]选取158名每日多次注射胰岛素的成人T2DM患者开展了一项多中心、随机对照临床试验,干预组佩戴CGM,对照组行常规护理,随访24周后发现几乎每天使用CGM的患者HbA1c虽有下降,然而两组患者的生活质量无明显差异。与Beck的研究结果不同,Volčanšek等^[17]对25名每日多次注射胰岛素的老年糖尿病患者进行的一项横断面调查显示,患者对使用CGM的满意度很高,考虑该研究中有一半为T1DM患者造成了两项研究结果的差异。此外,有研究招募122名未用餐时胰岛素的T2DM患者为其提供CGM及相关培训,12周后根据患者报告,发现患者糖尿病痛苦感降低,生活质量改善^[18]。因此,CGM用于T2DM患者可提高其生活质量,降低疾病相关痛苦感等。现实生活中,口服降糖药物的T2DM患者占糖尿病人群的大部分,国内目前尚未报道该类患者使用CGM对生活质量的改善,建议未来加强CGM对T2DM患者生活质量的关注并进行相关研究,将CGM的应用扩大到T1DM及用胰岛素治疗的T2DM患者之外。

2.4 CGM对T2DM患者睡眠情况的影响 T2DM患者睡眠情况与血糖之间有较强相关性^[19]。然而目前关于二者关系的研究均为观察性研究。T2DM患者睡眠与血糖研究发现睡眠时长与HbA1c的关系呈“U”形,每晚睡眠时间短或长于7~8h的患者的HbA1c更差^[20]。然而上述研究中的睡眠情况均基于患者的自我报告,可能与真实情况有差异。一项在中老年人中开展的社区观察性研究显示,采用活动记录仪和CGM以客观记录患者睡眠觉醒状态和血糖水平,发现夜间睡眠时间与血糖变异性直接相关,较长的夜间睡眠时间对胰岛素敏感性产生有益影响,减少T2DM患者的能量摄入量,降低餐后高血糖的风险,减少白天血糖变异性^[21]。睡眠作为T2DM患者重要且可改变的因素,预防睡眠问题可能成为今后管理T2DM的重点。近期国外已发表一项优化睡眠以改善成人T1DM患者血糖控制的随机对照研究,将120名T1DM患者分配至睡眠优化干预组或生活方式控制组,使用CGM、活动记录仪等客观记录12周干预后患者血糖、睡眠等结局^[22]。未来也应采用主客观工具相结合的方式监测T2DM患者睡眠时长、觉醒次数、睡眠效率等,进一步探讨优化T2DM患者睡眠情况的措施可否改善患者血糖控制及其他相关健康结局。

2.5 CGM对T2DM患者心理的影响 越来越多的证据表明,心理健康状况与血糖之间密切相关。然而这些研究成果无法

确定 CGM 显示的血糖结果与 T2DM 患者积极或消极情绪之间的因果关系。国外研究指出,CGM 可改善 T1DM 患者焦虑及抑郁情绪^[23],减轻对低血糖的恐惧和糖尿病困扰^[24]。针对 T2DM 患者,Wagner 等^[25]研究显示,积极情绪影响患者的 TIR 和葡萄糖水平。此外,有研究发现情绪和葡萄糖变异性之间也有密切关联^[26]。许国敏等^[27]的研究虽证实 CGM 联合心理疏导能帮助控制住院 T2DM 患者血糖,改善其不良情绪,提高生活质量。然而这种联合干预方式未能阐明 CGM 对 T2DM 患者健康结局的直接影响。今后干预性研究重点也可探索 CGM 对应用不同治疗方案的 T2DM 患者焦虑、抑郁、低血糖恐惧等心理健康的影响。

2.6 CGM 对 T2DM 患者经济成本的影响 CGM 在 T2DM 中的成本效益分析的研究有限。CGM 的使用可降低糖尿病心血管疾病、糖尿病足等并发症和患者死亡风险^[28]。尤其对于未用餐时胰岛素和进行初级保健的 T2DM 患者,使用 CGM 有更高的成本效益,可降低患者就诊次数和护理成本,提高医疗保健资源利用率^[29]。

3 T2DM 应用 CGM 面临的障碍

相较于 T1DM 患者,T2DM 患者使用 CGM 进行血糖监测的比例较低。国内外指南也仅推荐接受胰岛素强化治疗或血糖波动较大的 T2DM 患者使用 CGM 监测。CGM 的滞后性和患者经济水平是阻碍 T2DM 患者使用 CGM 的重要因素^[6]。

3.1 CGM 的滞后性 现有的 CGM 传感器经过工厂校准,准确性得以提高,然而学者发现除 CGM 类型及佩戴位置外,运动引起的生理性滞后时间也是 CGM 准确性的重要干扰因素,阻碍其在糖尿病患者中的推广应用。运动期间血糖浓度快速变化,组织间液与血液间葡萄糖浓度梯度增加,导致 CGM 无法真实反映运动期间血糖变化水平,间接影响患者胰岛素剂量及饮食决策调整^[30],这提醒必须尽可能准确了解运动引起的生理性滞后时长。Zaharieva 等^[31]使用较新的实时连续血糖监测技术让糖尿病患者进行 60 min 的有氧运动,发现与 SMBG 相比,有氧运动期间 CGM 血糖值滞后(12±11) min。考虑不同运动强度对 CGM 准确性的影响,Da Prato 等^[32]研究表明,相较于中等强度有氧运动,高强度间歇运动过程中 CGM 准确性更佳,达到了临床可接受范围。此外,2020 年 Dexcom 公司 CGM 技术再次更新,Guillot 等^[33]在研究 DexcomG6 葡萄糖传感器有氧运动、阻力运动和间歇运动期间的准确性时发现,运动类型并未影响 DexcomG6 CGM 精准度。CGM 对于糖尿病患者的管理优势日益突出,有氧运动期间 CGM 血糖值滞后时间长,高强度运动缩短 CGM 血糖滞后时间,运动类型不影响 CGM 精确性,国内 CGM 技术渐趋成熟,运动过程中,硅基、微泰等商家研发的 CGM 与 SMBG 及静脉血相比准确性如何,尚未见报道。

3.2 患者经济负担大 美国一项调查发现,每年糖尿病的直接医疗支出高达 2 370 亿美元^[34]。糖尿病患者每年花费 2 500~6 000 美元购买 CGM,而在发达国家,其医疗保险报销范围也仅覆盖 T1DM 和使用胰岛素治疗的 T2DM 患者,其他

糖尿病患者承受着较大经济负担^[35]。目前虽未见 CGM 在我国糖尿病患者中的成本报道,但我国糖尿病患者人数位列全球第一,基于人均收入及医保政策的局限,限制了 T2DM 患者使用 CGM 的可及性。

3.3 其他障碍因素 与 T1DM 患者感受相似,CGM 佩戴相关性疼痛、身体形象问题、警报疲劳、信息过载、皮肤刺激、对 CGM 不了解等问题也是 T2DM 患者使用 CGM 的障碍因素^[36]。Tilden 等^[37]分析 2 008 名糖尿病患者 3 年的 CGM 使用率,发现与居住在城市的患者相比,居住在偏远农村城镇的患者 CGM 使用率降低了 49%。此外有学者发现阻碍青少年 T2DM 患者使用 CGM 的因素不同于其他年龄段患者^[38]。在 T2DM 患者的整个生命周期中,使用 CGM 的感知负担和益处可能有所不同,中青年、老年人群也需加以关注。

4 未来发展方向

4.1 进一步加强 CGM 宣教,提高 T2DM 患者可接受性 CGM 可作为辅助教育工具改善 T2DM 患者血糖控制效果。CGM 的四大功能包括形成血糖波动曲线和动态葡萄糖图谱、指示性趋势箭头、发出警报、实现远程共享。医护人员在加强 CGM 理论及技能操作的同时,对患者的健康教育也应涵盖以上内容,帮助患者正确分析及确定血糖管理不佳原因,提高患者对警报的利用率和响应能力,提高糖尿病患者驾驭 CGM 技术的能力。Oser 等^[39]对 17 名新诊断成人 T2DM 患者进行 6 周 CGM 教育,包括发放 CGM 指导手册、进行日记记录等,随访 3 个月发现,患者糖尿病困扰、抑郁症状显著降低,67% 患者达到糖尿病缓解状态。因此,还应指导患者及时准确记录每日饮食、运动、用药等事件,借助 CGM 反馈功能,教育患者日常生活事件如何影响血糖。同时,患者应加强与医护人员和同伴的联系,强化 CGM 健康教育效果,增强改变自身行为的信心,提高对 CGM 的接受性^[10]。

4.2 改进 CGM 性能,提高 T2DM 患者 CGM 佩戴依从性 CGM 作为微创可穿戴设备被越来越多的应用^[40],但 CGM 佩戴体验阻碍糖尿病患者 CGM 佩戴依从性。首先是 CGM 准确性问题,血液和皮下组织葡萄糖浓度差异、传感器响应的滞后时间及用于校准的血糖试纸均影响 CGM 精准度。研究人员正试图使用更为先进的技术如代谢热构象、多项式拟合法等解决该问题,在未解决该问题前,应建议患者使用与 CGM 品牌相配套的血糖仪及试纸以期最大程度降低 CGM 的不准确性^[41-42]。其次为佩戴疼痛感问题,柔性 CGM 技术不断进步,研发出软质微针血糖监测技术和无创式皮肤可贴片血糖监测传感器,最大程度减少患者异物感和皮肤刺激^[43]。最后,CGM 外观也影响患者佩戴依从性,预计未来几年新兴纳米技术将极大推动 CGM 传感器微型化,改善 CGM 佩戴体验感。CGM 技术经过二十多年发展,其性能得到了长足发展,相信未来 CGM 将实现跨越式发展,惠及更多糖尿病患者,助力患者血糖管理。

4.3 短期或间歇使用 CGM,强化 T2DM 患者行为改变 长期使用 CGM 会加重患者经济负担,有研究表明,T2DM 患者短

期或间歇使用 CGM 会有较大获益^[14]。一项前瞻性、单组分配的试验招募 41 名青少年 T2DM 患者,发现佩戴 CGM 10 d 后,患者血糖监测次数增加,糖尿病管理整体情况改善^[14]。此外,T2DM 患者在开始治疗、强化生活方式改变时,每 2~3 个月或固定频率使用 CGM 也十分有用,还可节省成本^[44]。来自北美 8 个国家的一项多中心随机对照研究也表明口服多种药物的 T2DM 患者每月佩戴 1 次 CGM 持续 3 个月可对患者血糖产生适度的益处^[45]。T2DM 患者短期或间歇性使用 CGM 也可产生较高价值。临床探寻 T2DM 患者佩戴 CGM 的最佳时长截断点将促进血糖管理的同时减轻患者经济负担。

5 结 语

CGM 可改善不同治疗方案的 T2DM 患者血糖、自我管理行为及生活质量,影响患者睡眠和心理状况。然而 CGM 在 T2DM 患者中的应用还存在众多障碍因素。今后仍需更多研究深入探讨 CGM 健康教育、优化 CGM 性能、短期或间歇使用 CGM 在 T2DM 患者不同生命周期中的效果,从而为推动 CGM 在 T2DM 患者中的应用提供循证证据,促进我国 T2DM 患者血糖管理。

利益冲突 无

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