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Application of glyceimic risk index in the prevention and treatment of diabetes mellitus and its complications

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Abstract: The glyceimic risk index (GRI) is a comprehensive novel metric based on continuous glucose monitoring (CGM). By differentiated weighting different glucose ranges, it integrates the exposure levels and duration of both hypoglycemia and hyperglycemia, allowing for more precise quantification of glucose exposure. Recent studies have shown that GRI is independently associated with the risk assessment of diabetic microangiopathy and macroangiopathy complications. GRI also demonstrates high sensitivity in improving extreme glucose events in automated insulin delivery system intervention studies, showing advantages over traditional glucose monitoring metrics in certain aspects. GRI provides a new tool for predicting the risk of diabetic complications, evaluating intervention effects, and enabling personalized management. However further validation of clinical thresholds and general applicability of GRI is still needed.

Keywords: Glyceimic risk index; Continuous glucose monitoring; Diabetic complications; Blood glucose management; Diabetic microangiopathy; Diabetic macroangiopathy

Diabetes mellitus is a metabolic disease characterized by chronic hyperglycemia, whose long-term injuries are mainly manifested in the development and progression of microvascular and macrovascular complications. Studies have shown that the risks of retinopathy, nephropathy, neuropathy, and cardiovascular and cerebrovascular events are closely related to blood glucose control. Hemoglobin A1c (HbA1c) has long been used to reflect medium- to long-term average blood glucose levels, evaluate therapeutic effects, and assess the risk of complications. However, HbA1c only reflects the average state, making it difficult to capture short-term fluctuations and hypoglycemic risks. In populations with significant blood glucose fluctuations, it may underestimate the actual clinical risks. Additionally, it is susceptible to non-glycemic factors, which limits its interpretive value in some patients. In recent years, continuous glucose monitoring (CGM) technology has been widely used, transforming blood glucose monitoring from intermittent testing to continuous dynamic monitoring. Based on CGM data, indicators such as mean glucose, time in range (TIR), time below range (TBR), time above range (TAR), and

coefficient of variation (CV) have been proposed. These indicators enrich the blood glucose assessment system from multiple dimensions and have been widely used in clinical practice and research [1]. In practical application, it has been found that the above indicators are mostly single-dimensional, reflecting only one aspect of blood glucose control. They treat abnormal blood glucose levels of different severities equally, leading to the loss of key information. Accordingly, the assessment of blood glucose in diabetes has gradually shifted from "whether targets are met" to "risk assessment", with greater focus on the potential injuries of exposure to hyperglycemia and hypoglycemia. Under this concept, comprehensive indicators that integrate multi-dimensional CGM information and align with the logic of clinical risk assessment have become the research focus.

1 Development and composition principle of the GRI

The GRI was proposed against the clinical background of blood glucose management, with its core concept focusing on quantifying risk categories of hypoglycemia and hyperglycemia, rather than simply integrating multiple CGM indicators [2]. Studies have shown that hypoglycemia and hyperglycemia have different characteristics in clinical injury, treatment strategies, and patient prognosis, and should be evaluated as relatively independent yet equally important risk dimensions, rather than being combined into a single average-level indicator [2]. The construction of the GRI is based on clinicians' comprehensive judgments of overall blood glucose risk. In a relevant research, 330 diabetes experts with extensive clinical experience from different regions worldwide subjectively ranked 225 sets of CGM data, ranging from "optimal blood glucose control" to "poor blood glucose control". Researchers then converted each dataset into a percentile ranking from 0 to 100 using statistical methods, where 0 represents the lowest overall blood glucose risk and 100 represents the highest. This percentile ranking was regarded as clinicians' comprehensive evaluation of blood glucose risk levels. Based on this, researchers selected the most relevant parameter combinations from commonly used CGM indicators in the ambulatory glucose profile (AGP). Analysis results showed that four time-based indicators directly related to hypoglycemic and hyperglycemic exposure had the strongest explanatory power in predicting clinical scores: time in clinically significant hypoglycemia (VLow), time in hypoglycemia (Low), time in clinically significant hyperglycemia (VHigh), and time in

hyperglycemia (High) [3]. [Table 1] Using a linear regression model with the clinical percentile ranking as the dependent variable and the above four time-based indicators as independent variables, the final calculation formula for GRI was determined as: $GRI = 3.0 \times VLow + 2.4 \times Low + 1.6 \times VHigh + 0.8 \times High$. This formula integrates hypoglycemia- and hyperglycemia-related indicators with differentiated weights, with higher weights assigned to time spent in clinically significant abnormal blood glucose ranges. A lower GRI value indicates blood glucose control closer to the ideal state; a higher value suggests greater risk of hypoglycemia or hyperglycemia, and poorer overall blood glucose control quality. Compared to individual CGM indicators, GRI offers a more concise expression, enabling rapid identification of patients with poor blood glucose control or high-risk time periods. To enhance the intuitiveness of clinical application, the GRI can be visually displayed through a risk grid: with hypoglycemic risk and hyperglycemic risk as coordinate axes, the chart is divided into five blood glucose risk zones (A–E), corresponding to the 1–20, 21–40, 41–60, 61–80, and 81–100 percentiles, respectively. [Table 2] The risk grid not only presents the blood glucose control status of a large number of patients but also tracks the continuous blood glucose changes of individual patients, directly reflecting the type of abnormality and its changing trend. This visualization method aligns with clinicians' thinking when interpreting AGP profiles, helping to transform complex CGM data into actionable clinical information and providing a theoretical basis for the application of GRI in diabetes management and complication prevention [2].

Tab.1 Key CGM indicators and parameter definitions for GRI construction

Variable	Blood glucose range (mg/dL)	Unit	Weighting coefficient	Clinical significance
Time in clinically significant hypoglycemia (VLow)	< 54	%	High	Reflects severe hypoglycemic exposure, closely associated with risks of impaired consciousness, seizures, and adverse cardiovascular events.
Time in hypoglycemia (Low)	54-69	%	Moderate	Reflects mild to moderate hypoglycemic exposure, serving as a key source of cumulative hypoglycemic risk.
Time in clinically significant hyperglycemia (VHigh)	> 250	%	High	Reflects severe hyperglycemic exposure, significantly correlated with risks of acute metabolic disorders and chronic complications.
Time in hyperglycemia (High)	180-250	%	Moderate	Reflects persistent hyperglycemic load, acting as an important indicator of poor glycemic control.

Tab.2 GRI risk zone classification based on risk grid

Risk zone	Percentile range	Comprehensive blood glucose risk level	Clinical risk implication
A	1–20	Very low risk	Both hyperglycemia and hypoglycemia risks are at low levels, indicating good blood glucose control.
B	21-40	Low risk	Mild blood glucose abnormalities exist, but the overall risk is controllable.
C	41-60	Moderate risk	Hyperglycemia or hypoglycemia risks begin to accumulate, requiring clinical attention.
D	61-80	Relatively high risk	Significant exposure to blood glucose abnormalities, requiring high priority for intervention and management.
E	81-100	High risk	Hyperglycemia and/or hypoglycemia risks are significantly elevated, indicating poor blood glucose control.

2 Correlation and comparison between GRI and traditional blood glucose assessment indicators

To evaluate the clinical application value of the GRI, multiple studies have conducted correlation analyses between GRI and traditional blood glucose control indicators. Traditional indicators include HbA1c, MG, CV, TBR, TAR, and TIR. Studies have shown that GRI has a moderate positive correlation with HbA1c ($r=0.53$), indicating that overall blood glucose risk increases with elevated HbA1c levels. However, the correlation is not perfectly consistent, suggesting that GRI contains blood glucose risk information that cannot be fully reflected by HbA1c [4]. Among CGM-derived indicators, GRI has a strong negative correlation with TIR ($r=-0.90$), a moderate positive correlation with TAR ($r=0.63$), a relatively strong positive correlation with CV ($r=0.71$), and a relatively weak correlation with TBR ($r=0.37$). This indicates that GRI can simultaneously reflect both blood glucose exposure levels and fluctuation characteristics [5]. In the pediatric and adolescent population, a longitudinal study involving 719 children with type 1 diabetes mellitus showed that baseline GRI had a significant positive correlation with HbA1c at the same time point and during 3–12 months of follow-up (r-values ranging from

0.52-0.68), suggesting that GRI can stably reflect the changing trend of HbA1c over time [6]. Furthermore, real-world observational studies have further confirmed that: GRI maintains a significant negative correlation with TIR ($r=-0.94$), a positive correlation with the blood glucose variability indicator CV ($r=0.33$), and significant positive correlations with both MG and TAR ($P<0.05$). These findings demonstrate GRI's advantage in integrating information on hyperglycemia exposure [7-8].

Based on the above studies, it can be concluded that GRI characterizes the overall risk level of blood glucose abnormalities more comprehensively through the comprehensive quantification of both hyperglycemia and hypoglycemia risks. For example, the extremely strong negative correlation between GRI and TIR indicates that an increase in blood glucose risk is usually accompanied by a significant reduction in time spent within the target blood glucose range. Meanwhile, the relatively high correlation between GRI and CV further indicates that this indicator integrates blood glucose variability information to a certain extent. In contrast, the correlation between traditional HbA1c and CV is usually weak, which highlights GRI's potential advantage in reflecting blood glucose variability risk. For a detailed comparison between GRI and traditional blood glucose assessment indicators [5]. [Table 3]

Tab.3 Comparison of GRI with traditional glycemc assessment indicators

Comparison Dimension	GRI (Glucose Risk Indicator)	Traditional Blood Glucose Assessment Indicators (e.g., HbA1c, TIR, SD, MG, CV, etc.)
Core evaluation objective	Quantifies both hyperglycemia and hypoglycemia risks simultaneously, emphasizing risk orientation	Most indicators only reflect average levels or single fluctuation characteristics
Indicator composition	Integrates hyperglycemia and hypoglycemia risk components based on CGM data	Single or a small number of indicators, focusing on specific characteristics of one aspect
Sensitivity to extreme glucose values	Sensitive to both extreme hyperglycemia and hypoglycemia events	Some indicators (e.g., HbA1c) show insensitivity to extreme values
Risk differentiation ability	Directly reflects overall blood glucose risk level and its underlying sources	Overall risk requires comprehensive judgment by combining multiple indicators
Clinical interpretability	Results directly correspond to blood glucose risk levels, with a relatively clear interpretation path	Individual indicators have clear clinical meanings, but the interpretation of overall risk is fragmented
Clinical application Scenarios	Suitable for comprehensive assessment of blood glucose control risks and cross-patient comparison	Suitable for describing specific aspects of blood glucose control
Limitations	Relatively new methodology; clinical thresholds require further verification	Fragmented indicators that cannot independently reflect overall blood glucose risk

3 Application value of GRI in diabetes prevention and treatment

3.1 Application in the prevention and treatment of diabetic complications

Blood glucose fluctuations, recurrent hypoglycemia, and recurrent hyperglycemia are closely associated with

diabetic microvascular and macrovascular complications. By comprehensively quantifying the risk of blood glucose abnormalities, the GRI enables a more comprehensive assessment of complication risk, providing a tool for early warning and stratified management.

3.1.1 Application in the prevention and treatment of diabetic retinopathy (DR)

In studies on diabetic microvascular complications, prospective cohort evidence indicates that the GRI is independently and positively associated with the risk of developing DR. A study involving 1,204 patients with type 2 diabetes mellitus (T2DM) followed for a median of 8.4 years showed that higher GRI quartiles were associated with a greater risk of DR: the risk in the highest quartile was 53% higher than that in the lowest quartile, and 1 standard deviation increase in GRI was associated with approximately a 20% increase in DR risk. Additionally, a decrease in TIR was also linked to an elevated DR risk, but the predictive performance of the two indicators was generally comparable. Although the GRI was not significantly superior to TIR, its comprehensive risk profile integrating both hyperglycemia and hypoglycemia exposure can still provide supplementary information for DR risk stratification and individualized management [9].

3.1.2 Application in the prevention and treatment of diabetic nephropathy

Within the spectrum of diabetic microvascular complications, diabetic nephropathy is another major manifestation of target organ damage. Researchers analyzed the quantitative association between the GRI and urinary albumin excretion in patients with T2DM. A retrospective cohort included 866 patients, with the prevalence of microalbuminuria and macroalbuminuria being 36.6% and 13.9%, respectively. Multivariate logistic regression suggested that the GRI was associated with both microalbuminuria and macroalbuminuria, and independent of HbA1c. Compared with TIR, the GRI showed a greater magnitude of change with increasing urinary albumin-to-creatinine ratio, and the significance of the correlation remained after adjusting for HbA1c [10]. Furthermore, a cross-sectional study published by Japanese scholars in 2024 demonstrated the GRI's advantage in early warning of renal injury. The study found that the GRI was significantly correlated with urinary N-acetyl- β -D-glucosaminidase (uNAG/Cr), and this indicator increased before the onset of albuminuria, suggesting that the GRI can identify tubular injury at an earlier stage. Meanwhile, the GRI is highly sensitive to hyperglycemia-induced renal damage, maintaining an independent association after adjusting for factors such as estimated glomerular filtration rate (eGFR) [11].

3.1.3 Application in the prevention and treatment of diabetic peripheral neuropathy (DPN)

In the assessment of diabetic neuropathy, the GRI has demonstrated better clinical efficacy than traditional indicators. A cross-sectional study involving 862 patients with T2DM showed that the prevalence of DPN increased significantly with higher GRI quartiles. A multivariate analysis revealed that the highest GRI quartile had a significantly elevated risk of DPN compared with the lowest quartile, and this independent association remained after adjustment for HbA1c. In contrast, the association between TIR and DPN was no longer significant after adjusting for HbA1c. This difference may stem from the differential weighting of severe hyperglycemia and

hypoglycemia exposure in the GRI, which better reflects the risk of nerve damage from extreme glycemic events [12].

3.1.4 Application in the prevention and treatment of cardiovascular autonomic neuropathy (CAN)

CAN is significantly associated with the risk of cardiovascular events and mortality. The current standard method for evaluating CAN is cardiovascular autonomic reflex tests [13]. A cross-sectional study showed that 1 standard deviation increase in GRI was associated with a significant elevation in CAN risk. The area under the receiver operating characteristic (ROC) curve for GRI was 0.85, which was superior to that of TIR. Risk stratification analysis revealed that the prevalence of CAN in patients in the highest GRI risk zone (Zone E) was as high as 85.7%. Studies have indicated that GRI has the strongest correlation with heart rate variability and CAN severity, and its predictive value is independent of HbA1c, better reflecting the risk of nerve damage caused by extreme blood glucose fluctuations [14].

3.1.5 Application in the prevention and treatment of diabetic foot

Given the role of peripheral neuropathy and lower extremity vascular disease in the development of diabetic foot, studies have found that GRI is significantly and positively associated with the risk of diabetic foot and serves as an independent predictor. After multivariate adjustment, each 10-unit increase in GRI was associated with an approximately 11.5% increase in the risk of diabetic foot, while each 10% increase in TIR was associated with an approximately 13.3% decrease in risk. ROC analysis showed that GRI had better sensitivity than HbA1c in predicting diabetic foot. Researchers believe that GRI can comprehensively reflect the cumulative effect of extreme blood glucose exposure, providing advantages in risk assessment for severe terminal complications [15].

3.1.6 Application in the prevention and treatment of diabetic macrovascular complications

In the risk assessment of macrovascular complications, a Japanese multicenter study showed that GRI is significantly associated with arterial stiffness and vascular lesion characteristics. After adjusting for traditional risk factors, GRI remains positively correlated with brachial-ankle pulse wave velocity (baPWV) and negatively correlated with mean carotid gray-scale median (Mean-GSM), suggesting its ability to reflect arterial structural and functional damage. Compared with TIR, GRI captures the risks of vascular endothelial oxidative stress and atherosclerosis more comprehensively through weighted consideration of extreme hyperglycemia and hypoglycemia, and has stronger clinical warning value [16]. A 2024 study published by a Chinese research team enrolled 342 patients with T2DM. The results showed that GRI is independently associated with baPWV and can predict its increase beyond classic cardiovascular risk factors. Patients with high GRI levels also exhibited a higher incidence of microvascular complications,

suggesting that GRI is consistent in identifying comprehensive systemic macrovascular and microvascular damage [17].

In summary, as a comprehensive blood glucose risk indicator, GRI not only has significant predictive value in microvascular complications but also is independently associated with early pathological phenotypes of macrovascular disease. Existing evidence supports its application potential in clinical diabetes management and individualized risk assessment, especially in compensating for the limitations of traditional indicators such as HbA1c and TIR.

3.2 Application in comprehensive blood glucose management

In intervention studies of automated insulin delivery (AID) systems, particularly advanced hybrid closed-loop (AHCL) systems, the GRI is emerging as a core endpoint for measuring the quality and safety of blood glucose control as a novel comprehensive assessment indicator. Studies have shown that after switching from traditional multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII) to an AHCL system (e.g., Tandem t:slim X2 Control-IQ), patients experience a significant reduction in GRI. In adults, GRI decreases by an average of 23.5% after 6 months of intervention, with simultaneous improvements in both hyperglycemia and hypoglycemia risks [18]. Similar benefits have been observed in children with type 1 diabetes mellitus: after 6 months of applying AHCL system, the mean GRI score drops from 35.66 to 22.83, and the proportion of children in the lowest risk zone (Zone A) increases from 20% to 42% [19]. GRI demonstrates higher sensitivity than traditional TIR in evaluating the efficacy of AHCL interventions. An analysis of the MiniMed 670G system showed that while TIR improved by 22%, the risk reduction measured by GRI reached as high as 41% over the same period. This indicates that GRI can capture the clinical value of closed-loop systems in reducing extreme blood glucose risks more comprehensively. This sensitivity stems from GRI's higher weighting of extremely low blood glucose (<54 mg/dL) and extremely high blood glucose (>250 mg/dL), addressing the limitations of TIR in assessing hypoglycemic risk and extreme glycaemic events [20]. Furthermore, the improvement in GRI brought about by AHCL systems is rapid and sustained. Real-world studies confirm that GRI improves significantly as early as 1 month after system switching, and this effect remains stable for up to 12 months [21]. Notably, the beneficial effects of AHCL on GRI is independent of the patient's baseline treatment modality: the magnitude of risk index reduction is consistent regardless of whether patients previously used MDI or insulin pumps. Even in patients with impaired awareness of hypoglycemia (IAH), a population with greater management challenges, AHCL intervention still leads to significant GRI improvement.

Based on this evidence, the academic community currently recommends including GRI as a standard outcome measure in closed-loop clinical trials, and

advocates for a target of $GRI \leq 40$ for clinical management of patients with type 1 diabetes mellitus [20]. In summary, GRI not only quantifies improvements in overall blood glucose risk during AHCL system interventions but also sensitively captures extreme glycaemic events, providing a reliable basis for adjusting individualized treatment plans and long-term management.

4 Limitations and prospects

Although the GRI has shown potential in diabetes glycaemic management and complication risk assessment, it still has several limitations. First, the current weighting of GRI is mainly based on expert consensus, and its generalizability across diverse populations (such as children, elderly patients, and those with gestational diabetes mellitus) requires further validation. Second, there is a lack of standardized GRI thresholds and grading criteria in existing studies, with no widely recognized clinical cutoff values established. Third, as a comprehensive risk indicator, GRI should serve as a supplement, rather than a replacement for HbA1c and TIR. In clinical practice, GRI should be used in conjunction with TIR and HbA1c for comprehensive assessment to achieve more accurate risk stratification.

Future research should focus on the following priorities: first, validate the independent incremental value of GRI in predicting diabetic complications through large-scale prospective cohort studies; second, explore the applicability and develop population-specific optimization strategies for special groups, such as patients with gestational diabetes and elderly individuals with T2DM; third, integrate large-scale CGM data with intelligent analytical tools to enable prediction of high-risk glucose trajectories and implement early targeted interventions; finally, establish a standardized joint reporting system that uniformly adopts GRI, TIR, and HbA1c in both clinical trials and real-world studies, thereby enhancing the comparability, operability, and clinical utility of these indicators.

In summary, GRI is a novel CGM-based comprehensive indicator that can sensitively capture extreme glucose risks and has demonstrated unique value in predicting diabetic complications and evaluating therapeutic interventions. Future large-scale, multicenter, prospective studies are needed to establish evidence-based clinical thresholds for GRI and promote its widespread integration into clinical guidelines and practice.

Conflict of Interest None

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· 学术前沿 ·

葡萄糖风险指数在糖尿病及其并发症防治中的应用进展

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摘要: 葡萄糖风险指数(GRI)是一种基于连续血糖监测(CGM)的综合性新指标,通过对不同程度的血糖范围进行差异化加权,整合低血糖和高血糖暴露的程度和时长,能够实现更精确量化血糖暴露水平的目标。近期研究显示,GRI与糖尿病微血管及大血管病变的风险评估具有独立相关性,并在自动化胰岛素递送系统干预研究中对极端血糖事件的改善具有较高敏感性,在一些方面表现出了优于传统血糖监测指标的优势。GRI为糖尿病并发症风险预测、干预效果评价及个体化管理提供了新的工具,但仍需进一步验证其临床阈值和应用普适性。

关键词: 葡萄糖风险指数; 连续血糖监测; 糖尿病并发症; 血糖管理; 糖尿病微血管病变; 糖尿病大血管病变
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Keywords: Glycemc risk index; Continuous glucose monitoring; Diabetic complications; Blood glucose management; Diabetic microangiopathy; Diabetic macroangiopathy



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糖尿病是一种以慢性高血糖为特征的代谢性疾病,其长期危害主要表现为微血管和大血管并发症的发生与进展。研究表明,视网膜病变、肾病、神经病变及心脑血管事件风险与血糖控制密切相关。糖化血红蛋白(hemoglobin A1c, HbA1c)长期以来被用于反映中长期平均血糖水平,评估疗效和并发症风险。然而,其仅体现平均状态,难以反映短期波动和低血糖风险,在血糖波动较大人群中可能低估真实临床风险,且易受非血糖因素影响,限制了部分患者中的解释价值。近年来,连续血糖监测(continuous glucose monitoring, CGM)技术广泛应用,实现了血糖从间断检测向连续动态监测的转变。基于CGM数据,提出了平均血糖、血糖目标范围内时间(time in range, TIR)、血糖低于目标范围时间(time below range, TBR)、血糖高于目标范围时间(time above range, TAR)及血糖变异系数(coefficient of variation, CV)等指标,从多维度丰富了血糖评估体系,已在临床与研究中广泛应用^[1]。在实际应用中发现,上述指标多为单一维度,仅反映血糖控制的某一侧面,对不同严重程度的异常血糖进行同等处理,导致关键信息丢失。基于此,糖尿病血糖评估逐渐由“是否达标”转向“风险评估”,更加关注高、低血糖暴露的潜在危害。在该理念下,整合CGM多维信息并贴近临床风险判断逻辑的综合指标成为研究重点。

1 GRI的提出及构成原理

GRI是在血糖管理的临床背景下提出的,其核心理念是量化低血糖和高血糖两类风险,而非简单整合多个CGM指标^[2]。研究显示,低血糖和高血糖在临床危害、处理策略及患者预后方面具有不同特征,应作为相对独立但同等重要的风险维度进行评价,而非合并为单一平均水平指标^[2]。GRI的构建以临床医生对整体血糖风险的综合判断为基础。在相关研究中,330名来自全球不同地区、具有丰富临床经验的糖尿病专家,对225份CGM数据进行了主观排序,范围从“血糖控制最佳”到“血糖控制最差”。随后,研究者通过统计方法将每份数据转换为0~100的百分位数排名,其中0表示整体血糖风险最低,100表

示风险最高。该百分位数排名被视为临床医生对血糖风险水平的综合评价。基于此,研究者从动态血糖图谱(ambulatory glucose profile, AGP)中常用的CGM指标中筛选出与临床风险评估最相关的参数组合。分析结果显示,与低血糖和高血糖暴露直接相关的四项时间指标在预测临床评分中具有最强解释力,分别为:临床显著低血糖时间(VLow)、低血糖时间(Low)、临床显著高血糖时间(VHigh)以及高血糖时间(High),详见表1^[3]。基于线性回归模型,以临床百分位数排名为因变量、上述四项时间指标为自变量,最终确定GRI的计算公式为: $GRI=3.0 \times VLow+2.4 \times Low+1.6 \times VHigh+0.8 \times High$ 。该公式通过差异化权重整合低血糖与高血糖相关指标,其中临床显著的异常血糖时间被赋予更高权重。GRI数值越低,提示血糖控制越接近理想状态;数值越高,则表明低血糖或高血糖风险较大,整体血糖控制质量较差。相比单项CGM指标,GRI表达更简洁,可快速识别血糖控制不良的患者或高风险时段。为增强临床应用的直观性,GRI可通过风险网格进行可视化展示:以低血糖风险和高血糖风险为坐标轴,将图表划分为五个血糖风险区(A~E),分别对应第1~20、21~40、41~60、61~80、81~100百分位数,详见表2。风险网格不仅可呈现大量患者的血糖控制情况,还可跟踪单个患者的血糖连续变化,直观反映异常类型及变化趋势。这种可视化方式与临床医生解读AGP图谱的思路一致,有助于将复杂CGM数据转化为可操作的临床信息,为GRI在糖尿病管理及并发症防治中的应用提供理论基础^[2]。

2 GRI与传统经典血糖评估指标的相关性及比较

为了评估GRI的临床应用价值,多项研究对其与传统血糖控制指标进行了相关性分析。传统指标包括HbA1c、平均血糖(mean glucose, MG)、CV、TBR、TAR及TIR。研究显示,GRI与HbA1c呈中度正相关($r=0.53$),提示整体血糖风险随HbA1c水平升高而增加,但相关性并非完全一致,说明GRI包含了HbA1c无法全面反映的血糖风险信息^[4]。在CGM衍生指标方面,GRI与TIR呈高度负相关($r=-0.90$)、与TAR呈中度正相关($r=0.63$)、与CV呈较强正相关($r=0.71$),而与

表1 GRI构建所采用的关键CGM指标及其参数定义

Tab.1 Key CGM indicators and parameter definitions for GRI construction

指标	血糖(mg/dL)	单位	权重系数	临床意义
临床显著低血糖时间(VLow)	<54	%	较高	反映严重低血糖暴露,与意识障碍、癫痫及心血管不良事件风险密切相关
低血糖时间(Low)	54~69	%	中等	反映轻至中度低血糖暴露,是低血糖风险累积的重要来源
临床显著高血糖时间(VHigh)	>250	%	较高	反映严重高血糖暴露,与急性代谢紊乱及慢性并发症风险显著相关
高血糖时间(High)	180~250	%	中等	反映持续性高血糖负荷,是血糖控制不佳的重要标志

TBR相关性相对较弱($r=0.37$),表明其能够同时反映血糖暴露水平与波动特征^[5]。在儿童及青少年人群中,一项纳入719例1型糖尿病患儿的纵向研究显示,基线GRI与同期及随访3~12个月的HbA1c均呈显著正相关(r 值为0.52~0.68),提示GRI能稳定反映HbA1c随时间变化趋势^[6]。此外,真实世界观察性研究进一步证实,GRI与TIR持续呈显著负相关($r=-0.94$),并与血糖变异性指标CV呈正相关($r=0.33$),同时与MG及TAR均表现显著正相关($P<0.05$),显示GRI在整合高血糖暴露信息方面的优势^[7-8]。基于以上研究可以得出GRI通过对高、低血糖风险的综合量化,更全面地刻画了血糖异常的整体风险水平。例如,GRI与TIR之间极强的负相关关系表明,血糖风险的升高通常伴随着靶范围内血糖时间的显著减少。同时,GRI与CV的较高相关性进一步说明,该指标在一定程度上整合了血糖波动性信息,而传统HbA1c与CV之间的相关性通常较弱,这凸显了GRI在反映血糖变异风险方面的潜在优势,而GRI与传统血糖评估指标的比较详见表3^[5]。

表2 基于风险网格的GRI风险区划分

Tab.2 GRI risk zone classification based on risk grid

风险区	百分位数范围	综合血糖风险水平	临床风险含义说明
A	第1~20百分位	极低风险	高、低血糖风险均处于较低水平,血糖控制状态良好
B	第21~40百分位	低风险	存在轻度血糖异常,但整体风险可控
C	第41~60百分位	中等风险	高血糖或低血糖风险开始累积,需引起临床关注
D	第61~80百分位	较高风险	血糖异常暴露明显,干预与管理需求较高
E	第81~100百分位	高风险	高血糖和/或低血糖风险显著升高,提示血糖控制不佳

表3 GRI与传统血糖评估指标的比较

Tab.3 Comparison of GRI with traditional glycemic assessment indicators

对比维度	GRI	传统血糖评估指标(如HbA1c、TIR、SD、MG、CV等)
核心评价目标	同时量化高血糖风险与低血糖风险,突出风险导向	多数指标仅反映平均水平或单一波动特征
指标构成	基于CGM数据整合高血糖风险分量与低血糖风险分量	单指标或少量指标,侧重某一方面特征
血糖极端值的敏感性	对高、低血糖极端事件均较为敏感	部分指标(如HbA1c)对极端值不敏感
风险区分能力	可直接反映总体血糖风险水平及其来源	风险需结合多个指标综合判断
临床解释性	结果可直接对应血糖风险高低,解释路径相对清晰	单项指标临床含义明确,但整体风险解释分散
临床应用场景	适用于综合评估血糖控制风险及比较不同患者	适用于描述血糖控制的某一具体方面
局限性	方法相对较新,临床阈值仍需进一步验证	指标碎片化,难以单独反映总体血糖风险

注:SD,标准差。

3 GRI在糖尿病防治中的应用价值

3.1 在糖尿病并发症防治中的应用 血糖波动及反复低血糖、高血糖与糖尿病微血管和大血管并发症密切相关。GRI通过综合量化血糖异常风险,可更全面评估并发症风险,为早期预警和分层管理提供工具。

3.1.1 在糖尿病视网膜病变(diabetic retinopathy, DR)防治中的应用 在糖尿病微血管并发症研究中,前瞻性队列证据表明GRI与DR发生风险呈独立正相关。一项纳入1204例2型糖尿病(type 2 diabetes mellitus, T2DM)患者、随访中位8.4年的研究显示,GRI四分位数越高,DR风险越大,最高组风险较最低组增加53%,且GRI每升高1个标准差,DR风险增加约20%。同时,TIR降低亦与DR风险升高相关,但两者在预测效能上总体相当。尽管GRI未显著优于TIR,其整合高、低血糖暴露的综合风险特征,仍可为DR风险分层和个体化管理提供补充信息^[9]。

3.1.2 在糖尿病肾病防治中的应用 在糖尿病微血管病变的谱系中,糖尿病肾病是另一主要靶器官损伤表现。针对T2DM患者,研究者分析了GRI与尿白蛋白排泄的量化关联。回顾性队列共纳入866例患者,微量白蛋白尿和大量白蛋白尿的发生率分别为36.6%和13.9%。多变量logistic回归提示GRI与微量及大量白蛋白尿均相关,并且独立于HbA1c。相比TIR,GRI随尿白蛋白-肌酐比值升高的变化幅度更大,且在校正HbA1c后仍保持显著性^[10]。此外,日本学者于2024年发表的横断面研究显示,GRI在早期肾损伤预警中具有优势。研究发现GRI与尿N-乙酰-β-D-氨基葡萄糖苷酶(uNAG/Cr)显著相关,且该指标在尿白蛋白阳性前即升高,提示GRI可更早识别肾小管损伤。同时,GRI对高血糖诱导的肾损害高度敏感,在校正估算肾小球滤过率等因素后仍保持独立相关性^[11]。

3.1.3 在糖尿病周围神经病变(diabetic peripheral neuropathy, DPN)防治中的应用 在糖尿病神经病变评估中,GRI显示出优于传统指标的临床效能。横断面研究纳入862例T2DM患者,结果表明DPN患病率随GRI四分位数升高而显著增加。多变量分析显示,最高GRI组发生DPN的风险较最低组显著升高,且在校正HbA1c后仍保持独立相关性。相比之下,TIR在校正HbA1c后与DPN的关联不再显著。该差异可能源于GRI对严重高、低血糖暴露的差异化加权,更能反映极端血糖事件对神经损伤的风险^[12]。

3.1.4 在糖尿病心血管自主神经病变(cardiovascular autonomic neuropathy, CAN)防治中的应用 CAN

与心血管事件及死亡风险显著相关,目前评价CAN的标准方法是心血管自主神经反射试验^[13]。一项横断面研究显示GRI每增加1个标准差,CAN风险显著升高。GRI的受试者工作特征(receiver operating characteristic, ROC)曲线下面积为0.85,优于TIR。风险分层分析显示,GRI最高风险区(E区)患者的CAN患病率高达85.7%。研究表明,GRI与心率变异性及CAN严重程度相关性最强,且其预测价值独立于HbA1c,更能反映极端血糖波动导致的神经损伤风险^[14]。

3.1.5 在糖尿病足防治中的应用 鉴于周围神经及下肢血管病变在糖尿病足发生中的作用,研究发现GRI与糖尿病足风险显著正相关,并为其独立预测因子。多因素调整后,GRI每增加10个单位,糖尿病足风险增加约11.5%,而TIR每增加10%风险下降约13.3%。ROC分析显示,GRI在预测糖尿病足方面的灵敏度优于HbA1c。研究认为,GRI能综合反映极端血糖暴露的累积效应,对严重终末并发症的风险评估具有优势^[15]。

3.1.6 在糖尿病大血管病变防治中的应用 在大血管病变风险评估中,日本多中心研究表明,GRI与动脉僵硬度和血管病变特征显著相关,在校正传统危险因素后仍与臂踝脉搏波传导速度(brachial-ankle pulse wave velocity, baPWV)正相关、与颈动脉平均灰阶中值(mean gray-scale median, Mean-GSM)负相关,提示其可反映动脉结构与功能损伤。相比TIR,GRI通过对极端高、低血糖的加权,更全面捕捉血管内皮氧化应激及动脉粥样硬化风险,具有更强的临床预警价值^[16]。中国研究团队于2024年发表的研究纳入342例T2DM患者,结果显示GRI与baPWV独立相关,可在经典心血管危险因素之外预测其升高。高GRI水平患者同时表现出更高的微血管并发症发生率,提示GRI在识别全身大血管与微血管综合损伤方面具有一致性^[17]。

综上,GRI作为综合性血糖风险指标,不仅在微血管并发症中具有显著预测价值,也与大血管早期病理表型独立相关。现有证据支持其在糖尿病临床管理和个体化风险评估中的应用潜力,尤其可弥补HbA1c与TIR等传统指标的局限性。

3.2 在血糖综合管理中的应用 在自动化胰岛素递送系统中,特别是高级混合闭环(advanced hybrid closed-loop system, AHCL)系统的干预研究中,GRI作为一种新型的综合评估指标,正逐渐成为衡量血糖控制质量和安全性的核心终点。研究表明,从传统

的每日多次注射(multiple daily injections, MDI)或持续皮下胰岛素输注(continuous subcutaneous insulin infusion, CSII)切换至AHCL系统(如Tandem t:slim X2 Control-IQ)后,患者的GRI会显著下降,在成人中干预6个月后GRI可平均降低23.5%,且高血糖风险和低血糖风险均得到同步改善^[18]。在儿童1型糖尿病患者中同样观察到类似获益,使用AHCL系统6个月后,平均GRI评分从35.66降至22.83,且处于最低风险区(A区)的患儿比例从20%提高至42%^[19]。GRI在评估AHCL干预效果方面展现出比传统TIR更高的灵敏度。一项针对MiniMed 670G系统的分析显示,虽然TIR提升了22%,但同期GRI的风险降幅高达41%,这表明GRI能更全面地捕捉到闭环系统在降低极端血糖风险方面的临床价值。这种灵敏度源于GRI对极低血糖(<54 mg/dL)和极高血糖(>250 mg/dL)赋予了更高的权重,弥补了TIR在评估低血糖风险和血糖极值方面的不足^[20]。此外,AHCL系统带来的GRI改善具有快速且持续的特点,真实世界研究证实,患者在切换系统1个月后GRI即可显著改善,且这种效果可稳定维持长达12个月^[21]。值得注意的是,AHCL对GRI的改善作用不受患者基线治疗方式的影响,无论患者此前使用MDI还是胰岛素泵,其风险指数的降幅均保持一致。即使是对于管理难度较大的“低血糖感知受损(impaired awareness of hypoglycemia, IAH)”患者,AHCL干预同样能带来显著的GRI改善。基于这些证据,目前学术界建议将GRI纳入闭环临床试验的标准结局指标,并提倡将GRI \leq 40作为1型糖尿病患者临床治疗的目标^[20]。综上所述,GRI在AHCL系统干预中不仅能够量化整体血糖风险的改善,还能敏感捕捉极端血糖事件,为个体化治疗方案调整与长期管理提供可靠依据。

4 局限性与展望

尽管GRI在糖尿病血糖管理和并发症风险评估中显示出潜力,但仍存在若干局限。首先,GRI当前权重主要基于专家意见,其普适性在不同人群(如儿童、老年患者及妊娠糖尿病)中尚需进一步验证。其次,研究中采用的GRI阈值和分级标准不统一,缺乏广泛认可的临床阈值。第三,GRI作为综合风险指标应作为HbA1c和TIR的补充,而非替代。在临床实践中,GRI应结合TIR与HbA1c进行综合评估,以获得更准确的风险判定。

未来研究则应重点关注以下方面:首先通过前瞻性队列研究验证GRI对糖尿病并发症预测的独立

增量价值;其次探索特殊人群(如妊娠糖尿病、老年T2DM患者)中的适用性与优化方案;再次是结合大规模CGM数据与智能化分析手段,实现高风险血糖轨迹预测与早期干预;最后建立标准化联合报告体系,在临床试验和真实世界研究中统一采用GRI与TIR、HbA1c,以提升指标的可比性、可操作性及临床应用价值。

综上,GRI是一个基于CGM的新型综合指标,能够敏感捕捉极端血糖风险,在糖尿病并发症预测、治疗干预评价中显示出独特价值。未来需要通过更大规模、多中心、前瞻性研究来确立其临床阈值,并推动其在指南与实践中的广泛应用。

利益冲突 无

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