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Status of continuous glucose monitoring use and management in tertiary hospitals of China: a cross-sectional study

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ABSTRACT

Objective This study aims to reveal the use and management status of continuous glucose monitoring (CGM) in tertiary hospitals in China and to determine the potential factors affecting the application of CGM, based on which more effective solutions would be produced and implemented.

Design An online, cross-sectional study was conducted from October 2021 to December 2021.

Setting Eighty-three tertiary hospitals in China were involved.

Participants Eighty-three head nurses and 281 clinical nurses were obtained.

Outcome Current condition of CGM use and management, the factors that hinder the use and management of CGM, scores of current CGM use and management, as well as their influencing factors, were collected.

Results Among the 83 hospitals surveyed, 57 (68.7%) hospitals used CGM for no more than 10 patients per month. Seventy-three (88.0%) hospitals had developed CGM standard operating procedures, but only 29 (34.9%) hospitals devised emergency plans to deal with adverse effects related to CGM. Comparably, maternal and children's hospitals were more likely to have a dedicated person to assign install CGM than general hospitals (52.2% vs 26.7%). As for the potential causes that hinder the use and management of CGM, head nurses' and nurses' perceptions differed. Head nurses perceived patients' limited knowledge about CGM (60.2%), the high costs of CGM and inaccessibility to medical insurance (59.0%), and imperfect CGM management systems (44.6%) as the top three factors. Different from head nurses, CGM operation nurses considered the age of CGM operators, the type of hospital nurses worked in, the number of patients using CGM per month and the number of CGM training sessions as potential factors ($p<0.05$).

Conclusions The study provides a broad view of the development status of CGM in China. Generally speaking, the use and management of CGM in China are not yet satisfactory, and more efforts are wanted for improvement.

STRENGTHS AND LIMITATIONS

⇒ This study reflected the current situation of continuous glucose monitoring (CGM) use and management, as well as the factors hindering the use and management of CGM to a certain extent.
⇒ Due to the cross-sectional nature of the study, we were unable to determine the causal relationship between the current status of CGM use management and its influencing factors.
⇒ The majority of the questionnaires were distributed to tertiary hospitals, resulting in few secondary and primary hospitals being reached by the survey.

INTRODUCTION

[1–3]As of 2021, approximately 537 million adults in the world are living with diabetes mellitus (DM), 6.7 million lives lost to DM, and the global health expenditure due to DM is about $966 billion.[4 5] In 2018, the prevalence of adult DM reached 14.3% in the USA, and only 21.2% of these patients achieved glycaemic control goals.[1–3] Over the past decade, the incidence of DM has rapidly increased in low-income and middle-income countries than that in high-income countries, while the absence of robust policies and healthcare systems in low-income regions has made the conditions for the prevention and treatment of DM even worse.

[6–9]The incidence of DM in China has also been increasing annually, with a prevalence rate reaching 10.6% in 2021. China has the highest proportion of individuals with DM. Currently, about 140 million adults are suffering from DM, and healthcare expenditures have reached up to $165 billion.[10] The overall awareness, treatment and control rates of DM among patients in China are 36.7%, 32.9% and 50.1% respectively, which are relatively low.

To treat DM effectively, a collaboration between the government, social sources, patients and manufacturers of medical technologies is required.[1] Effective tools can be used to improve its management, thereby reducing the incidence of complications and

premature deaths associated with diabetes. In the past decades, significant advancements were made in DM management tools and technologies that have resulted in the improvement in glycaemic control of patients with DM. Continuous glucose monitoring (CGM) is one such tool. Although routine self-monitoring of blood glucose is still commonly performed, CGM has shown admirable advantages in providing comprehensive and continuous information on blood glucose, identifying hidden hyperglycaemia and hypoglycaemia, revealing trends in patients' blood glucose fluctuations, and reducing pain from frequent acupuncture.

[11–14]CGM has been used in medical institutions in various countries, and its implementation has increased annually.[15] In the USA, the use of CGM among those with type 1 DM increased from 7% in 2010–2012 to 30% in 2016–2018.[16] In Germany, the prevalence of CGM use increased from 3% in 2006 to 38% in 2017.[17] In Korea, the use of CGM increased from 1.4% in 2010 to 39.3% in 2019.[18 19] However, the use of CGM needs to be improved further.[19–23] Previous studies have indicated that the factors impacting the use of CGM include CGM-associated costs, accessibility to healthcare providers, inadequate CGM training of healthcare workers, limited CGM-related knowledge of patients and inadequate support from CGM manufacturers.[24] A review demonstrated that the use of CGM in hospitalised patients has numerous advantages with minimal risks.[25–27] To promote the standardised use and management of CGM, China published the *Chinese Clinical Guidelines for Continuous Glucose Monitoring* in 2009, which were updated in 2012 and 2017.

In several hospitals in China, implantation, operation and day-to-day management of CGM are generally performed by nurses and head nurses of the endocrinology department. As the key performers, they are familiar not only with the use and management of CGM at their hospitals but also with other details such as the types of CGM used, management system, insurance coverage, training, assessment, etc. In this study, we surveyed the nurses and the head nurses who were involved in CGM use and management in different hospitals in China, attempting to know more about the current status of CGM use, management and the relevant affecting factors. The findings produced would offer targeted information that would help improve the use and management of CGM in future practice. To the best of our knowledge, previously few studies were conducted on a nationwide survey of the status of CGM use and management in China.

METHODS

Patient and public involvement

The public and the patients were not involved in the design, conduct, reporting or dissemination of this survey.

Study design and setting

This online, cross-sectional survey was conducted among nurses who were in charge of CGM use and management in China from October to December 2021. Head nurses and nurses from the department of endocrinology of the 83 hospitals in China were involved. Two different survey forms, *the CGM system use and management questionnaire for head nurses* (abbreviated as *the form for head nurses*) and *the CGM system use and management questionnaire for nurses* (abbreviated as *the form for nurses*), were prepared separately for head nurses and nurses in advance.

Participants and sample size

A convenience sample of 83 head nurses and 281 nurses involved in CGM use and management from 83 tertiary hospitals were enrolled in the survey. Of note, the 'type of hospital' in this study refers to a hospital that is either general or specialised according to the patient population it serves, 'others' refers to the facilities that provide medical care exclusively to children and women; while the 'class of hospital' refers to a hospital with a certain level of medical technology according to the reviews conducted every 4 years by the National Health Commission. Only one head nurse who was responsible for data analysis, decision-making and management system recommendation in the implementation of CGM was selected for each hospital. First, the link to *the form for head nurses* was sent via WeChat (a mobile-based instant social application issued by Tencent. It functions similarly to LINE, Twitter, WhatsApp and Facebook, and has been broadly used by Chinese cell phone subscribers) to several national diabetes committees, the Diabetes Group of the Paediatric Nursing Alliance of the China Children's Medical Centre, the 27th Chinese Nursing Association's Expert Group on Intravenous Therapy and the Nursing Management Group of the China Children's Hospital Branch, etc. The inclusion criteria for the head nurses were the following: (1) who were familiar with the current status of CGM use and management in the hospital and could provide relevant documents; (2) who were currently working as a staff member (not on sick or personal leave); and (3) who signed informed consent to participate in the survey. Then, the head nurses were entrusted to distribute the link of *the form for nurses* to the nurses responsible for CGM operation. Inclusion criteria for the nurses were as follows: (1) were able to install the CGM system independently; (2) were currently working as a staff (not on sick or personal leave); and (3) agreed to participate voluntarily. We collected general information on hospitals, head nurses and clinical nurses, and special information on the use and management status of CGM and its influencing factors.

Questionnaires

The questionnaires were developed in three steps between October and November 2021. First, the initial drafts of the questionnaires were formed based on an extensive research review following the study's purpose. Second,

we invited five specialists in diabetes care to discuss the drafts. Based on the suggestions, we revised the drafts item by item. Finally, a pilot survey was conducted on five head nurses and eight operating nurses. The participants took 2–5 minutes to complete the survey. Then, the questionnaires underwent another revision based on the participants' feedback.

Head nurses completed *the form for head nurses*. The final questionnaire consists of questions regarding the demographic information of head nurses, the type of CGM used in their hospitals, usage frequency of CGM, insurance coverage, management department, inspection situation, the process of quality control, personnel responsibilities, the current status of assessment and training, etc.

CGM-operating nurses completed *the form for nurses*. The final questionnaire consists of a section for the nurses' demographic information of the nurses and another section containing the assessment questions (15 items), which were divided into three dimensions: CGM performance requirements and document management, personnel responsibilities, training and examination. Possible scores were 0, 1 and 2, separately corresponding to 'no', 'not sure' and 'yes'. Cronbach's alpha for the questionnaire was 0.867.

Data collection

This survey was carried out in December 2021. Two Wenjuanxing hyperlinks for the questionnaires were distributed to head nurses and CGM-operating nurses via WeChat. Informed consent was provided on the home page on clicking the link. The respondents were required to complete the form within 2 weeks. Two researchers evaluated the validity of the questionnaires.

Bias control

Strict quality control was implemented to ensure data authenticity. Uniform instructions were used to explain the purpose of the study, the content of this survey, and the inclusion and exclusion criteria; and we adopted the logic control design for the electronic questionnaires. Each WeChat account user was only allowed to fill up the form only once, and the process was anonymous. The form could not be submitted until all the questions were completed. Those with the same option were excluded by the two-person data verification methods.

Data analysis

Statistical analysis was performed using the dedicated SPSS V.23.0 software. For descriptive statistics, data were expressed as frequency, proportions and percentages for binary variables (ie, sex), and mean and SD for continuous variables (ie, score). The inferential statistics for the two groups included the χ^2 test for categorical variables and the independent samples t-test for continuous variables. One-way analysis of variance was used to compare the continuous variables in three or more groups. Then a multiple linear regression method was employed to analyse the factors affecting the CGM management evaluation score. A p value of <0.05 was considered significant. The independent variables were assigned as follows: (1) age: 20–30 years old=1, 31–40 years old=2 and >40 years old=3; (2) type of hospitals: general hospital=1, maternal and child healthcare hospital or children's hospital=2; (3) the average number of the patients monitored with CGM per month: ≤10 cases = 1, 11–30 cases=2 and >30 cases=3; (4) numbers of training received: ≤3 times=1, 4–6 times=2, ≥7 times=3.

Figure 1 Regional distribution of the 83 hospitals and 281 nurses that were surveyed

RESULTS

General characteristics

A total of 83 head nurses completed *the form for head nurses*. All of them satisfied the inclusion criteria and were enrolled in the study. The individuals came from various provinces in China, and their regional distribution was both balanced and representative of the target population. The regional distribution of the 83 hospitals and 281 nurses is shown in figure 1. The inclusion and exclusion process was summarised in figure 2. Of the 83 hospitals, 60 were general hospitals (72.3%) and 23 were maternal and children's hospitals (27.4%); according to the results of the questionnaire, there are 15 training bases for diabetes specialist nurses (17.9%). Two hundred and eighty-seven operators completed *the form for nurses*; however, six forms with the same option for all items were excluded, leaving a total of 281 valid responses with an efficiency rate of 97.9%.

Head nurses' perception regarding the status of CGM use and management

The current status of CGM use and management in the 83 hospitals is minutely shown in table 1. According to the survey responses, the patients who used CGM were patients with type 1 diabetes (92.8%), patients with type 2 diabetes who experience large blood sugar fluctuations (72.3%), patients with type 2 diabetes requiring intensive

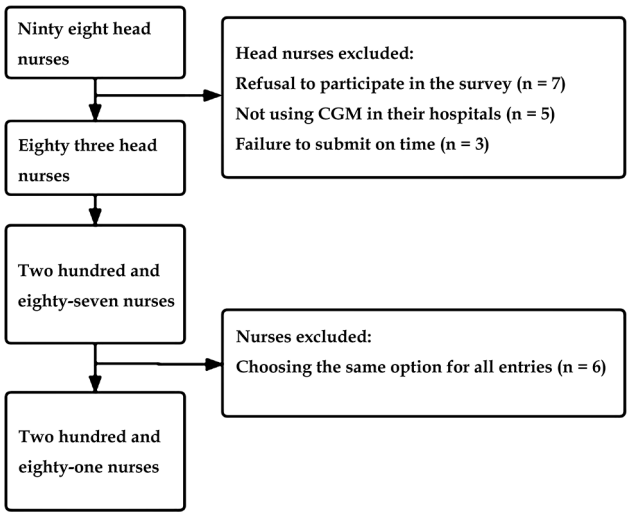

Figure 2 The inclusion and exclusion process of participants. CGM, continuous glucose monitoring.

insulin therapy (68.7%), patients with gestational diabetes or people with diabetes who are pregnant now (49.4%) and patients with specific types of diabetes (45.8%). In the opinion of head nurses, the top four factors that hinder the application and management of CGM were as follows: patients' lack of recognition of CGM (60.2%), high and non-reimbursable costs associated with CGM (59.0%), inadequate management mechanism (44.6%) and refusal of patients to use CGM (36.1%).

Nurses' perception regarding the status of CGM use and management

The scores of the variables related to CGM use and management based on the nurses' responses were summarised in table 2. Nurses did not think highly of CGM use and management. Univariate analysis of the results showed that the age of nurses, the type of hospital that nurses worked at, the average number of patients per month and the frequency of training received were statistically significant variables.

The score for CGM use and management status was assigned as the dependent variable, the variables of statistical significance in the univariate analysis were taken as independent variables, and a multiple linear regression method was used to identify the independent factors. The nurses' age, type of hospital, the average number of patients per month and frequency of training were the factors independently affecting the score, as shown in table 3. In maternal and children's hospitals, the younger the operators, the higher the number of patients that they handled per month; moreover, the higher the frequency of training, the higher the score for CGM use and management.

DISCUSSION

The introduction of CGM into Chinese hospitals was relatively late. People are still unfamiliar with this new generation of glucose monitoring technology in general.[28] This study surveyed 83 hospitals in various regions of China. According to the data issued by the National Health Commission, by the end of 2021, there are a total of 3275 tertiary hospitals in China. Despite accounting only for 4% of them, the hospitals surveyed represent the best hospitals in our country. About 140 million adults are living with DM in China. However, as shown in this study, approximately 70% of the hospitals surveyed use CGM for no more than 10 patients per month; moreover, the CGM management teams that should comprise the staff from medical offices, nursing departments, laboratory departments, equipment departments and other departments have not yet been well established possibly due to the low frequency of CGM usage and lack of sufficient attention.[15–17 29 30] In developed countries, such as Germany and the USA, nearly 40% of patients with DM are using CGM, while 52.6% of children with type 1 DM underwent CGM in Norway, with the usage rate continuing to increase. Therefore, we indirectly infer that the utilisation rate of CGM among patients with DM in China is much lower than that in some developed countries, which also indicates the need for improvement in its clinical application.

In this survey, the most commonly used type of CGM was retrospective CGM and followed by real-time CGM. Notably, the results were obtained only based on the responses of the participants, not based on quantitative data. Strictly following the standard procedures is a prerequisite for the successful implementation of CGM. This survey showed that 12.0% of the hospitals still lack CGM standard operating procedures, which should be established as soon as possible to facilitate the standardised adoption of CGM. The CGM-related risks have not as well gained adequate recognition.[29 31 32] CGM-related adverse events include contact dermatitis, allergies and hypoglycaemia. The survey shows that only one-third of the hospitals have formulated emergency plans to manage these adverse events. Besides, 37.3% of the hospitals have yet not implemented regular supervision over the use and management of CGM, indicating that the quality check systems in some hospitals still require continuous improvement.

Of the hospitals surveyed in this study, around two-thirds of them conducted CGM training and evaluation using slightly different methods, but they still preferred offline forms of training and demonstration.[33 34] With the persistence of COVID-19, many online education or training platforms have emerged and become increasingly mature, and the use of virtual reality and other new technologies in the teaching and training process has also been widely explored. Hospitals can make full use of such tools and techniques for CGM training while reducing the risk of aggregation and infection. The entry 'regularly conduct operational assessments on personnel operating CGM' gained the lowest score, which served as a reminder that hospitals should regularly carry out CGM-related training based on actual situations in the future while implementing operational assessments to consolidate the knowledge and skills of trainees.

Table 1 Use and management status of CGM (n=83)

Category	N (%)	Hospital type		P value
		General hospital	Other type	
The type of CGM most commonly used CGM				0.710*
Retrospective CGM	29 (34.9)	21 (25.3)	8 (9.6)	
Real-time CGM	53 (63.9)	38 (45.8)	14 (16.9)	
Miscellaneous	2 (2.4)	1 (1.2)	1 (1.2)	
Number of patients using CGM per month				0.057*
≤10	57 (68.7)	38 (45.8)	19 (22.9)	
11–30	15 (18.1)	11 (13.3)	4 (4.8)	
> 30	11 (13.3)	11 (13.3)	0 (0)	
Is CGM covered by insurance?				0.978
Yes	25 (30.1)	18 (21.6)	7 (8.4)	
Partial	35 (42.2)	25 (30.1)	10 (12.0)	
No	23 (27.7)	17 (20.5)	6 (7.2)	
The organisation or department that manages CGM				0.580*
Clinical laboratory	1 (1.2)	1 (1.2)	0 (0)	
Medical department	3 (3.6)	2 (2.4)	1 (1.2)	
Medical ward	78 (94.0)	57 (68.8)	21 (25.3)	
No	1 (1.2)	0 (0)	1 (1.2)	
Whether CGM is regularly inspected?				0.835
Yes	52 (62.7)	38 (45.8)	14 (16.9)	
Whether CGM-related training and evaluation is conducted?				0.690*
Training only	24 (28.9)	17 (20.5)	7 (8.4)	
Training and evaluation	55 (66.3)	39 (47.0)	16 (19.3)	
No training and evaluation	4 (4.8)	4 (4.8)	0 (0)	
Ways of conducting CGM-related training				1.000*
Offline theory explanation and operation demonstration	71 (85.5)	51 (61.4)	20 (24.1)	
Online theory explanation and operation demonstration	10 (12.0)	7 (8.4)	3 (3.6)	
Theoretical explanation only	0 (0)	0 (0)	0 (0)	
Demonstration of operation only	2 (2.4)	2 (2.4)	0 (0)	
CGM is managed by a dedicated person				1.000*
Yes	65 (78.3)	47 (56.7)	18 (21.7)	
Has a CGM standard operating procedure				0.270*
Yes	73 (88.0)	51 (61.4)	22 (26.5)	
Has a CGM emergency plan				0.620
Yes	29 (34.9)	20 (24.1)	9 (10.8)	
Has a dedicated person to install CGM				0.028
Yes	28 (33.7)	16 (19.3)	12 (14.4)	
Professional level needed to install CGM				0.156*
Primary	7 (8.4)	4 (4.8)	3 (3.6)	
Middle	32 (38.6)	20 (24.1)	12 (14.5)	
Senior	4 (4.8)	3 (3.6)	1 (1.2)	
No job title required	40 (48.2)	33 (39.8)	7 (8.4)	
Has a dedicated staff to explain the CGM monitoring report				0.099
Yes	42 (50.6)	27 (32.5)	15 (18.1)	
Professional level needed to explain the CGM monitoring report				0.051*

Continued

Table 1 Continued

Category	N (%)	Hospital type		P value
		General hospital	Other type	
Primary	3 (3.6)	1 (1.2)	2 (2.4)	
Middle	31 (37.3)	19 (22.9)	12 (14.5)	
Senior	14 (16.9)	10 (12.0)	4 (4.8)	
No job title required	35 (42.2)	30 (36.1)	5 (6.0)	
Is quality control performed regularly ?				0.204
Yes	59 (71.1)	45 (54.2)	14 (16.9)	
Do you think CGM use management is insufficient ?				1.000*
Yes	70 (84.3)	50 (60.2)	21 (24.1)	

*Fisher exact test.
CGM, continuous glucose monitoring.

Table 2 CGM use and management scores

Dimensions and items	Score (x±s)
Dimension 1. Performance requirements and file management	**5.30±1.27**
1.1 Whether the accuracy of CGM has been assessed before entering your hospital/ department	1.77±0.54
1.2 There are CGM standard operating procedures	1.85±0.49
1.3 There are CGM failure causes and emergency treatment plan	1.67±0.69
Dimension 2. Responsibilities of personnel	**5.01±2.33**
2.1 Dedicated person to manage CGM	1.50±0.85
2.2 Dedicated person to install CGM	1.20±0.96
2.3 Dedicated person to interpret the CGM report	1.52±0.79
2.4 Think that CGM use management is insufficient	0.80±0.78
Dimension 3. Training and evaluation	**12.01±4.49**
3.1 Regularly carry out training related to CGM	1.34±0.87
3.2 The content of the training is reasonable, comprehensive and clear	1.65±0.63
3.3 The methods of conducting CGM-related training are scientific and diversified	1.56±0.71
3.4 The frequency of training is reasonable	1.53±0.73
3.5 The duration of each training is reasonable	1.69±0.60
3.6 Periodically conduct a theoretical evaluation	1.70±0.62
3.7 Regularly conduct operational evaluation	1.23±0.91
3.8 Satisfied with the overall effect of CGM training	1.32±0.88

CGM, continuous glucose monitoring.

[18 19 35 36]Similar to the studies conducted in the USA, Korea and other countries, head nurses in this study agreed that the factors hindering the use and management of CGM include patients' limited knowledge about CGM (60.2%), the high costs of CGM and inaccessibility to medical insurance (59.0%) and the non-standardised CGM management systems (44.6%). This finding suggests that while conducting CGM training for medical staff, it may be necessary to invite relevant patients and healthcare personnel to participate in the training to increase their awareness related to CGM.[37 38] The insurance coverage of CGM-related expenses has been advocated in the literature.[13 39] For instance, the Australian government fully covers CGM-related costs for patients with DM under 21 years old and those with gestational diabetes.[29 40 41] In Norway and the USA, the CGM-related expenses of patients with DM are also reimbursed, although the reimbursement rates vary. China has not yet included CGM within the coverage of national medical insurance. CGM-related costs can be reimbursed for only a fraction of patients through social funds or research funds. This may be one of the main factors hindering the wide adoption

Table 3 Multiple linear regression analysis results of CGM use and management evaluation scores (n=281)

Variable	Regression coefficient	P value	95% CI
Age of nurse	−1.37	0.029	−2.595 to 0.138
Hospital type	3.18	0.001	1.314 to 5.045
The average number of use cases per month	1.71	0.001	0.716 to 2.699
The frequency of training	1.81	0.001	0.791 to 2.830

Note: R=0.369, R^2=0.136, adjusted R^2=0.124, F=10.882, P<0.001.
CGM, continuous glucose monitoring.

of CGM in China. More generous insurance policies give patients more chances to access CGM.

Data obtained from the CGM-operating nurses showed other factors that hinder the use and management of CGM. Multiple linear regression analysis demonstrated that the major factors that independently affect CGM use and management are the age of CGM operators, type of hospital, number of patients using CGM per month and number of CGM training sessions. The age of CGM operators showed a negative correlation with CGM use and management score, while the other three factors showed a positive correlation with CGM use and management score. The older the operator, the lower their evaluation of the status of CGM use and management. This may be due to the fact that older operators have more experience: therefore, any problems that existed during the process of CGM use and management can be identified more easily. The score of CGM use and management in children's hospitals or maternity and childcare hospitals was better than that in general hospitals as such hospitals usually pay more attention to device management given the uniqueness of their patient populations. Hospitals that performed CGM on no more than 10 patients per month scored lower, mainly due to the lack of opportunity to practise CGM use and management. Few training sessions also produced low scores, suggesting the need for increased training opportunities.

The major limitations of this study at least included (1) the inability to reveal the causal relationship between CGM management and use due to the inherent deficiencies of cross-sectional studies; and (2) in this study, questionnaires were distributed mostly to tertiary hospitals. As a result, few secondary hospitals and primary hospitals were reached by the survey, which makes it impossible to obtain the current status of CGM use and management in secondary and primary hospitals.

CONCLUSION

In summary, by investigating the status of CGM use and management in 83 tertiary hospitals, this study provides a broad view of the development status of CGM in China, problems that existed in CGM use and management, and the factors affecting its promotion, etc. In general, the use and management of CGM in China are far from satisfactory. Many efforts are warranted to promote its use and improve its management, such as insurance coverage of related expenses, provision of more training sessions, provision of more opportunities to practise and development of a standardised management system.

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Contributors LC wrote the first draft. LW conceptualised and designed the study,and responsible for the overall content as the guarantor. XL and LC performed the statistical analysis. QL and HD supervised the research. YZ and ZS reviewed the draft.

Competing interests None declared.

Patient and public involvement Neither the patients nor the public were involved in the design, conduct, reporting or dissemination plans of our research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Institutional Review Board, Children's Hospital of Chongqing Medical University. Ethical approval number is 2021-241. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available upon reasonable request. The datasets used and/or analysed during the current study are available from the corresponding author (LW) on reasonable request.

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STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-5
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	-
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5
		(*b*) Describe any methods used to examine subgroups and interactions	5
		(*c*) Explain how missing data were addressed	-
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	-
		(*e*) Describe any sensitivity analyses	5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5-6
		(b) Give reasons for non-participation at each stage	5-6
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6-9
Outcome data	15*	Report numbers of outcome events or summary measures	6-9
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-9

		(*b*) Report category boundaries when continuous variables were categorized	6-9
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	9-10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	2
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9-10
Generalisability	21	Discuss the generalisability (external validity) of the study results	9-10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	10

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.