Development and assessment of the Quality of Life Instruments for Chronic Diseases-Gout (QLICD-GO) (V2.0)

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Abstract
Objective To develop and assess the Quality of Life Instruments for Chronic Diseases-Gout QLICD-GO (V2.0).
Methods The instrument was developed using a programmatic decision-making method to combine the general module of the Quality of Life Instruments for Chronic Diseases and a new specific module. The instrument was assessed by measuring the quality of life of 116 patients with gout.
Results The QLICD-GO (V2.0) included 28 items from the general module of chronic diseases and 12 items in three facets from the specific module. In addition to the field of physiological function, the internal consistency reliability of other fields and dimensions of the instrument was > 0.7, and the split-half reliability was > 0.5. Three common factors were extracted from the specific module, with a cumulative variance contribution rate of 57.54%. The standardized response means of the specific module and the whole instrument were 0.94 and 1.20, respectively.
Conclusions The QLICD-GO (V2.0) has good reliability, validity, and responsiveness. The instrument comprehensively and objectively reflects the quality of life of patients with gout, and it can be used to assess treatment regimens developed by medical staff.

Key Points
• The QLICD-GO (V2.0) has been developed for patients with gout based upon the foundation of the QLICD-GM.
• The QLICD-GO reflects the clinical signs and symptoms, drug-related side effects, and psychological changes specific to patients with gout.
• Based on the assessment results, the QLICD-GO (V2.0) has good reliability, validity, and responsiveness.
• QLICD-GO (V2.0) can objectively and comprehensively reflect the QOL of patients with gout and can be used by clinical staff to assess treatment regimens.

Keywords Gout · Instrument · Quality of life · Reliability · Responsiveness · Validity

In recent years, despite the variations in reports across countries, there has been a clear upward trend in the incidence of gout [1]. Gout is a chronic disease caused by an elevation in the serum urate level [2]. In Western Europe, 1 to 2% of adults have been affected by gout, while the proportions have reached 4% in developed countries such as the USA and the UK [3]. Male patients outnumber female patients at a ratio of approximately 3:1. The prevalence of gout in China is about 1.1%, which is increasing year by year. The age of gout is also becoming younger [4]. The prevalence of gout is increasing with socioeconomic development and changes in diet structure [5].

At present, the universal scale on the quality of life of gout patients reported at home and abroad mainly

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includes the following: Health Status Questionnaire (MOS SF-36), WHO Quality of Life Questionnaire Short Form (WHOQOL-BREF), and Stanford Health Assessment Questionnaire (HAQ) [6–8]; specific scales for gout mainly include the following: Gout Assessment Questionnaire (GAQ2.0) and Tophus Impact Questionnaire 20 (TIQ-20) [9, 10]. The disadvantage of the universal scale is that it is not formulated for the disease gout, so there is no specificity of the disease. Therefore, the development of a gout quality of life measurement scale suitable for China’s national conditions which can not only compare horizontally with other diseases but also reflect the changes of intervention is the main direction of our research. The specific module of this scale is developed for gout patients, which has strong pertinence and can reflect the unique physical, psychological, and social function changes and drug side effects of gout patients in the diagnosis and treatment of their quality of life.

Chronic Diseases-Gout (QLICD-GO, V2.0) is a part of the Quality of Life Scale for patients with chronic diseases (QLICD), which is developed for gout patients on the basis of the common module (QLICD-GM). This system includes a general module (QLICD-GM, V1.0), which can be used with all types of chronic disease patients, and specific modules for different diseases, with each module being used for only the relevant disease [11]. Based on the Quality of Life Instruments for Chronic Diseases (QLICD-GM, V1.0) in China developed by Wan et al., the Quality of Life Instruments for Chronic Diseases-Gout (QLICD-GO, V2.0) was formulated and used to assess patients with gout during clinic visits between October 2015 and December 2016. The results are reported below.

**Methods**

**Instrument description**

The QLICD-GO (V2.0) was developed by combining the widely recognized general module of the Quality of Life Instruments for Chronic Diseases (QLICD-GM) with a specific module for gout. This general module, consisting of 28 items in three domains (physical function, psychological function, and social function). With reference to relevant literature and QOL instruments (universal and specific instruments) for patients with gout from China and abroad and in combination with clinical expertise on gout, we proposed a pool of 34 health-related QOL items specifically for patients with gout, covering gout-induced impacts on the physical, psychological, and social functioning of patients, and drug-related side effects. Each potential item for the gout-specific module was analyzed at meetings of the topic panel and core panel. Thirteen items for the specific module were selected and were organized into a patient questionnaire and a medical staff questionnaire. Based on five methods to screen items and the opinions of clinical experts, a 12-item gout-specific module was formed. The QLICD-GO (V2.0) is divided into four aspects, including physical symptoms and signs (six items), functional limitation to daily life (one item), common drug-related side effects (two items), and unique psychological effects (three items).

A five-point Likert scoring method is used, with possible scores between 1 and 5 or between −5 and −1. The higher the score of a positive item, the better the QOL; the greater the absolute value of the score of a negative item, the worse the QOL. For positive items, there is no need to convert, the original score is the item score, for reverse items, it is necessary to “forward transform,” that is, subtract the original score from 6 to get the item score, the person who fills in the first level will get 5 points, the person who fills in the second level will get 4 points, and so on. The total scores in patients with gout was calculated according to the rules for QLICD-GO (V2.0).

**Data collection**

The investigator briefly explained the purpose of the survey and distributed the instrument to the patients, who filled in the instrument independently according to their actual conditions. Because most patients with gout were outpatients, the subjects fill out the instrument on the day of initial consultation and on the day of subsequent consultation.

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**Study subjects and methods**

**Subjects**

The subjects were 161 patients with a confirmed diagnosis of gout in the Department of Rheumatology and Immunology in the First Affiliated Hospital of Shenzhen University (Shenzhen Second People’s Hospital) and the Affiliated Hospital of Guangdong Medical University between October 2015 and December 2016. The diagnostic criteria were based on the 2015 American College of Rheumatology/European League Against Rheumatism Gout Classification Criteria [12]. The eligible patients had basic literacy skills. Pre- and posttreatment quality of life (QOL) assessments were performed after informed consent was obtained.
Instrument assessment

After conversion of item scores, the raw score (RS) in each aspect was calculated and converted to a standard score (SS) according to the range method to facilitate comparison between items. The SS of a domain was obtained by subtracting the lowest possible score of the domain \(S_{\text{min}}\) from the RS of the domain, the difference was divided by the range of the RS of the domain, and the result was multiplied by 100. The calculation formula is \[ SS = \frac{(RS - S_{\text{min}})}{(S_{\text{max}} - S_{\text{min}})} \times 100. \] (3). The assessment covered the reliability (internal consistency reliability and split-half reliability), validity (content validity, construct validity, and criterion validity), and responsiveness (comparison of pre- and posttreatment mean scores, standardized response mean [SRM]) of the instrument. In this study, we use SF-36 as the calibration standard, because the calibration validity is lack of gold standard, and SF-36 is a widely recognized tool for measuring QOL [13].

Statistical analysis

SPSS 21.0 statistical software was used for data entry and analysis. The statistical methods included the following two categories: methods for instrument item screening (coefficient of variation, correlation analysis, and factor analysis) and methods for instrument assessment (paired t-test and correlation analysis).

Results

General information

A total of 116 outpatients (aged 46.81 ± 16.38 years) with gout were investigated in this study. The details are presented in Table 1.

Reliability analysis

A total of 116 patients with gout were investigated using the QLICD-GO to analyze the internal consistency and split-half reliability of the general domain and specific domain. The Cronbach alpha coefficient of QLICD-GO in all fields is above 0.7 except for the physiological function field. The Cronbach's \(\alpha\) coefficients of the general domain, specific domain, and whole instrument were 0.84, 0.81, and 0.55, respectively; the split-half reliability coefficients of domains in the QLICD-GO were between 0.33 and 0.76. The split-half reliability coefficients of the general domain, specific domain, and whole instrument were 0.73, 0.65, and 0.89.

Table 1 General information of 116 patients with gout

| Category                  | Number of patients (N) | Constituent ratio (%) | Category                  | Number of patients (N) | Constituent ratio (%) |
|---------------------------|------------------------|-----------------------|---------------------------|------------------------|-----------------------|
| Sex                       | Male                   | 110                   | 94.8                      | Nationality            | Han                   | 116                   | 100          |
|                           | Female                 | 6                     | 5.2                       | Others                 | 0                     | 0                     |
| Educational level         | Primary school         | 8                     | 6.9                       | Occupation             | Worker                | 33                    | 28.4         |
|                           | Junior high school     | 35                    | 30.2                      | Farmer                 | 26                    | 22.4                  |
|                           | High school or technical secondary school | 39 | 33.6 | Teacher | 6 | 5.2 |
|                           | Junior college         | 19                    | 16.4                      | Cadre                  | 9                     | 7.8                   |
|                           |                        |                       |                           | Others                 | 29                    | 25.0                  |
| Health insurance          | Self-paying            | 109                   | 94.0                      | Household financial status | Poor | 8 | 6.9 |
|                           | Social health insurance| 7                     | 6.0                       | Fair                   | 99                    | 85.3                  |
|                           | Commercial health insurance | 0 | 0 | Good | 9 | 7.8 |
|                           | Rural Cooperative health insurance | 0 | 0 | | |
| Marital status            | Unmarried              | 19                    | 16.4                      | Clinical stage         | Intercritical stage (with tophi) | 2 | 1.7 |
|                           | Married                | 95                    | 81.9                      | Acute stage            | 86                    | 74.10                 |
|                           | Divorced               | 1                     | 0.9                       | Acute stage (with tophi) | 23 | 19.80 |
|                           | Widowed                | 1                     | 0.9                       | Chronic stage (with tophi) | 5 | 4.30 |
| Age                       |                        | 46.81 ± 16.38         |                           |                        |                       |                       |
respectively. Both coefficients showed relatively high reliability and good internal consistency of the instrument (see Table 2 for details).

Validity analysis

Content validity

The QLICD-GO has been developed in a stringent and programmatic manner under the QLICD system. The items of the instrument include dimensions and assessment contents required by the World Health Organization (WHO) and conforming to the definitions of health and QOL proposed by the WHO. These items cover the physical, psychological, and social status specific to patients with gout. The relatively good content validity of the QLICD-GO is justified on the basis of thorough discussion and screening by the expert panel.

Construct validity

Since assessment of the construct validity of the general module of the instrument has been completed at an early stage, only the construct validity of the specific module was assessed in this section, mainly using exploratory factor analysis and item-dimension correlation analysis.

Exploratory factor analysis: Bartlett’s test of sphericity of the specific module of the instrument yielded a χ² value of 471.93 (P < 0.001), indicating that the variables were not independent and were suitable for factor analysis. In addition, the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy was 0.76 in this study, indicating that factor analysis was suitable (factor analysis is not suitable when KMO is < 0.5). The principal component analysis method was used to extract common factors. According to the above discussion and eigenvalue > 1, three common factors were extracted for the instrument after varimax rotation. The cumulative variance contribution rate was 57.54%. Factor I included TAR7 and TAR10–TGO12 and mainly reflected the psychological changes in patients with gout; factor II included TAR1–TAR4 and mainly reflected the clinical symptoms and signs in patients with gout; factor III included TAR5, TAR6, TAR8, and TAR9, and it mainly reflected the persistent conditions and long-term drug-related side effects in patients with gout. The contribution rates of the three factors were 34.79%, 11.89%, and 10.86%, respectively. Among them, factor I had the highest contribution rate. Broad consistency between the items reflected by these factors and the results obtained after screening and discussion of specific module items in the instrument indicates relatively good construct validity of the specific module items. The specific module factors and the factor loading coefficients of items are presented in Table 3 and Fig. 1.

Item-dimension correlation: coefficients of correlation between each item of the QLICD-GO (V2.0) and the scores of the general module’s physical, psychological, and social domains and the gout-specific module were calculated. Correlation analysis showed relatively large coefficients of correlation between most items and their domains but small coefficients of correlation between these items and other domains, and the r values were mostly above 0.4. For example, the items of specific module unsurprisingly had closer correlations with the specific module areas than with the other three areas. It can be concluded that there were good correlations between QLICD-GO items and their dimensions and therefore satisfactory construct validity (see Table 4 for details).

Criterion validity

The role function and the emotional function domain of the SF-36 instrument were weakly correlated with domains of the QLICD-GO (coefficients of correlation < 0.4). For the remaining six domains of the SF-36 instrument, the coefficients of correlation with corresponding domains of the QLICD-GO were all > 0.4. The coefficients of correlation between the corresponding domains were statistically significant (P < 0.05; Table 5). The QLICD-GO therefore has relatively good criterion validity.

Responsiveness analysis

To evaluate the responsiveness of the QLICD-GO (V2.0), differences between pre- and posttreatment scores were calculated for each domain, the general module, and the whole instrument using the paired t-test, and the SRM was also calculated. The SRM is defined as the absolute ratio of the mean difference between pre- and posttreatment values to the standard deviation of the difference between pre- and posttreatment values. The analysis showed

### Table 2  Internal consistency reliability of the QLICD-GO

| Domain                  | Number of items | Cronbach’s α coefficient | Split-half reliability |
|-------------------------|-----------------|--------------------------|------------------------|
| Specific domain (SPD)   | 12              | 0.81                     | 0.65                   |
| General domain (GED)    | 28              | 0.84                     | 0.73                   |
| Physical domain (PHD)   | 9               | 0.49                     | 0.33                   |
| Psychological domain (PSD)| 11            | 0.79                     | 0.76                   |
| Social domain (SOD)     | 8               | 0.77                     | 0.72                   |
| Total (TOT)             | 40              | 0.55                     | 0.89                   |

SPD, specific domain; GED, general domain; PHD, physical domain; PSD, psychological domain; SOD, social domain; QLICD-GO, the Quality of Life Instruments for Chronic Diseases-Gout
significant differences between pre- and posttreatment scores for the domains, the general module, the specific module, and the whole instrument ($P < 0.05$). The SRMs were above 0.90 for the whole instrument and all domains except psychological function and social function, indicating that the QLICD-GO has favorable responsiveness and is sensitive in reflecting changes in the QOL of patients with gout. The details are presented in Table 6 and Fig. 2.

**Discussion and conclusion**

The QLICD-GO (V2.0) has been developed for patients with gout based upon the foundation of the QLICD system, namely, the general module of the QLICD (QLICD-GM). The QLICD-GO reflects the clinical signs and symptoms, drug-related side effects, and psychological changes specific to patients with gout. The QLICD-GO (V2.0) consists of two
parts, the mature general module and the specific module developed in this study, which includes 12 items (six items in clinical signs and symptoms, two items in drug-related side effects, and four items in unique psychological changes).

Item screening is one of the key steps in the development of any QOL instrument, which should adhere to the principles of high sensitivity, good representativeness, strong independence, sufficient certainty, and great

Table 4 Correlations between QLICD-GO items and their own domains

| Item | Physical function | Psychological function | Social function | Specific module |
|------|------------------|-----------------------|----------------|----------------|
| GPH1 | 0.534**          | 0.175                 | 0.188*         | 0.137          |
| GPH2 | 0.332**          | 0.031                 | 0.129          | 0.161          |
| GPH3 | 0.431**          | 0.271**               | 0.083*         | 0.218*         |
| GPH4 | 0.436**          | 0.012                 | 0.263**        | 0.279**        |
| GPH5 | 0.133            | 0.285**               | 0.145          | 0.407**        |
| GPH6 | 0.494**          | 0.067                 | 0.027          | 0.223*         |
| GPH7 | 0.573**          | 0.007                 | 0.014          | 0.354**        |
| GPH8 | 0.514**          | 0.025                 | 0.057          | 0.230*         |
| GPH9 | 0.318**          | 0.356**               | 0.054          | 0.226*         |
| GPH10| 0.537**          | 0.396**               | 0.208*         | 0.407**        |
| GPS1 | 0.337**          | 0.085                 | 0.289**        | 0.311**        |
| GPS2 | 0.167            | 0.402**               | 0.032          | 0.163          |
| GPS3 | 0.258**          | 0.073                 | 0.201*         | 0.156          |
| GPS4 | 0.237*           | 0.560**               | 0.118          | 0.260**        |
| GPS5 | 0.091            | 0.643**               | 0.105          | 0.378**        |
| GPS6 | 0.041            | 0.633**               | 0.192          | 0.492**        |
| GPS7 | 0.084            | 0.742**               | 0.127**        | 0.397**        |
| GPS8 | 0.046            | 0.612**               | 0.074          | 0.360**        |
| GPS9 | 0.146            | 0.671**               | 0.174          | 0.477**        |
| GPS10| 0.260**          | 0.041                 | 0.374**        | 0.234*         |
| GPS11| 0.115            | 0.555**               | 0.016          | 0.363**        |
| GSO1 | 0.214**          | 0.008                | 0.605**        | 0.220*         |
| GSO2 | 0.151            | 0.095                 | 0.492**        | 0.169          |
| GSO3 | 0.195*           | 0.147                 | 0.482**        | 0.052          |
| GSO4 | 0.084            | 0.005                 | 0.671**        | 0.036          |
| GSO5 | 0.109            | 0.020                 | 0.657**        | 0.080          |
| GSO6 | 0.027            | 0.385**               | 0.132          | 0.368**        |
| GSO7 | 0.246**          | 0.376**               | 0.350**        | 0.460**        |
| GSO8 | 0.183*           | 0.076                 | 0.569**        | 0.125          |
| TAR1 | 0.138            | 0.320**               | 0.216**        | 0.667**        |
| TAR2 | 0.189*           | 0.246**               | 0.122          | 0.455**        |
| TAR3 | 0.177            | 0.290**               | 0.075          | 0.691**        |
| TAR4 | 0.067            | 0.043                 | 0.162          | 0.125          |
| TAR5 | 0.105            | 0.239**               | 0.045          | 0.509**        |
| TAR6 | 0.049            | 0.319**               | 0.015          | 0.511**        |
| TAR7 | 0.024            | 0.127                 | 0.091          | 0.381**        |
| TAR8 | 0.013            | 0.007*                | 0.241*         | 0.368**        |
| TAR9 | 0.028            | 0.425**               | 0.083          | 0.741**        |
| TAR10| 0.020            | 0.358**               | 0.079          | 0.704**        |
| TAR11| 0.008            | 0.402**               | 0.152          | 0.774**        |
| TAR12| 0.098            | 0.194*                | 0.077          | 0.637**        |

**P < 0.01; *P < 0.05

GPH, gout instrument physical function question; GPS, gout instrument psychological function question; GSO, gout instrument social function question; TAR, gout instrument targeted question; QLICD-GO, the Quality of Life Instruments for Chronic Diseases-Gout.

$p < 0.05$; and $p < 0.01$ for each comparison.
significance [14]. Reliability refers to the repeatability or consistency of item scores [15]. Validity reflects the degree of conformity between the measured results of the instrument and the expected results [16]. Content validity refers to whether the selected items are capable of representing the characteristics of the measured content or subject [17]. Construct validity performs a factor analysis of all items based on the results of the survey, and classifies the items according to the loading of each item on each factor [18]. Responsiveness reflects the sensitivity to reflect changes in characteristic values of a subject [19]. Based on the assessment results, the QLICD-GO (V2.0) has good reliability, validity, and responsiveness. Zhang [20] has recommended 0.70 as the minimal Cronbach’s $\alpha$ coefficient of internal consistency that would indicate relatively good internal consistency reliability. The Cronbach’s $\alpha$ coefficient of the specific module was 0.81, and the split-half reliability was 0.65 in this study, indicating relatively good reliability of the specific module. The validity of the instrument is relatively good based on content validity, construct validity, and criterion validity. The instrument is sensitive to changes in QOL of patients with gout before and after treatment. The responsiveness of an instrument is considered relatively good if absolute SRM is > 0.8, moderate for an absolute SRM of about 0.5, and relatively poor for an absolute SRM of about 0.2 [21]. Here, the SRM was 0.94 for the specific module, and 1.2 for the whole instrument, indicating relatively good responsiveness of the QLICD-GO.

| Domain/Aspect | Pretreatment $\overline{x} \pm s$ | Posttreatment $\overline{x} \pm s$ | Paired $t$-test $t$ | $P$ | SRM |
|---------------|----------------------------------|----------------------------------|-------------------|-----|-----|
| **Physical function (PHD)** | | | | | |
| Basic physical function (BPF) | $59.09 \pm 15.04$ | $67.16 \pm 13.32$ | $-6.82$ | $<0.001$ | 0.63 |
| Independence (IND) | $59.34 \pm 20.24$ | $83.69 \pm 18.00$ | $-12.32$ | $<0.001$ | 1.14 |
| Energy and discomfort (EAD) | $40.30 \pm 20.86$ | $66.16 \pm 16.49$ | $-13.37$ | $<0.001$ | 1.24 |
| **Psychological function (PSD)** | $61.79 \pm 16.23$ | $68.03 \pm 14.08$ | $-5.52$ | $<0.001$ | 0.51 |
| Cognition (COG) | $63.69 \pm 18.50$ | $69.61 \pm 18.81$ | $-3.28$ | 0.001 | 0.30 |
| Emotion (EMO) | $58.74 \pm 19.67$ | $65.73 \pm 16.37$ | $-5.42$ | $<0.001$ | 0.50 |
| Will (WIL) | $74.35 \pm 23.65$ | $77.80 \pm 21.31$ | $-1.91$ | 0.059 | 0.18 |
| Personality (PER) | $66.81 \pm 25.91$ | $71.12 \pm 20.75$ | $-1.95$ | 0.054 | 0.18 |
| **Social function (SOD)** | $75.54 \pm 14.91$ | $78.29 \pm 12.51$ | $-3.03$ | 0.003 | 0.28 |
| Interpersonal communication (INC) | $81.47 \pm 15.85$ | $85.42 \pm 13.04$ | $-4.03$ | $<0.001$ | 0.37 |
| Social support (SSS) | $76.22 \pm 17.66$ | $76.29 \pm 14.44$ | $-0.05$ | 0.958 | 0.00 |
| Social role (SOR) | $65.63 \pm 22.35$ | $70.58 \pm 19.03$ | $-2.84$ | 0.005 | 0.26 |
| **General domain (GED)** | $63.38 \pm 11.92$ | $72.20 \pm 10.94$ | $-11.60$ | $<0.001$ | 1.08 |
| **Specific domain (SPD)** | $52.89 \pm 17.74$ | $64.62 \pm 14.71$ | $-10.08$ | $<0.001$ | 0.94 |
| Symptoms and signs (SAS) | $48.78 \pm 19.23$ | $74.21 \pm 15.88$ | $-15.28$ | $<0.001$ | 1.42 |
| Drug-related side effects (DSE) | $77.59 \pm 21.84$ | $71.98 \pm 22.64$ | $2.92$ | 0.004 | 0.27 |
| Psychological changes (PC) | $46.71 \pm 27.45$ | $46.55 \pm 25.94$ | 0.09 | 0.932 | 0.01 |
| **Total (TOT)** | $60.31 \pm 12.27$ | $69.98 \pm 10.95$ | $-12.95$ | $<0.001$ | 1.20 |

PHD, physical function; BPF, basic physical function; EAD, energy and discomfort; PSD, psychological domain; SOD, social function; INC, interpersonal communication; SSS, social support; SOR, social role; GED, general domain; SPD, specific domain; SAS, symptoms and signs; DSE, drug-related side effects; PC, psychological changes; QLICD-GO, the Quality of Life Instruments for Chronic Diseases-Gout.

The bold parts represent different large dimensions.
The QLICD-GO (V2.0) has been carefully developed according to an established scientific program, and it has shown good reliability, validity, and responsiveness in this initial assessment. It can objectively and comprehensively reflect the QOL of patients with gout and can be used by clinical staff to assess treatment regimens. The QLICD-GO (V2.0) was developed in the context of Chinese culture and provides a good basis and platform for measurement and assessment of the QOL of patients with gout in China.

By enabling systematic measurement of the QOL of patients with gout both before and after treatment, the QLICD-GO (V2.0) may aid in public health education and patient-centered clinical research. In addition, more samples are needed to refine the instrument and more efforts are needed to further improve the QOL of patients with gout.

**Abbreviations**
QLICD-GM: The Quality of Life Instruments for Chronic Diseases; QOL: Quality of life; RS: Raw score; SS: Standard score; SRM: Standardized response mean; KMO: Kaiser–Meyer–Olkin

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**Author contribution**
QL L and X L contributed equally to this work. QL L and CH W designed the study. XH X and XJ W did the literature search, study quality assessment, and data extraction. X L and P Z performed the statistical analysis and drafted the tables and figures. X L wrote the first draft of this analysis, and QL L helped to finish the final version. All authors approved the conclusions of our study.

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**Data availability**
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Declarations**

**Ethics approval and consent to participate**
All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Consent for publication**
Not applicable.

**Disclosures**
None.

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