Exploration of the Methods of Establishing the Minimum Clinical Important Difference Based on Anchor and Its Application in the Quality of Life Measurement Scale QLICP-ES (V2.0) for Esophageal Cancer

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Abstract

Background: The development of the minimum clinical important difference (MCID) can make it easier for researchers or doctors to judge the significance of research results and the effect of intervention measures, and improve the evaluation system of efficacy. This paper is aimed to calculate the MCID based on anchor and to develop MCID for esophageal cancer scale (QLICP-ES).

Methods: Q29 of EORTC QLQ-C30 was used as the subjective anchor to calculate the score difference between each domain at discharge and admission. MCID was established according to two standards, "one grade difference"(A) and "at least one grade difference"(B), and developed by three methods: anchor-based method, ROC curve method and multiple linear regression model.

Results: Most of the correlation coefficients of Q29 and various domains of the QLICP-ES were higher than 0.30. The rank of MCID values determined by different methods and standards were as follows: standard B > standard A, anchor-based method > ROC curve method > multiple linear regression model. The recommended MCID values of physical domain, psychological domain, social domain, common symptom and side-effects domain, the specific domain and the overall of the QLICP-ES were 7.8, 9.7, 4.7, 3.6, 4.3, 2.3 and 2.9, respectively.

Conclusion: Different methods have their own advantages and disadvantages, and also different definitions and standards can be adopted according to research purposes and methods. A lot of different MCID values were presented in this paper so that it can be easy and convenient to select by users.

Background

Esophageal cancer is the second most common solid intrathoracic malignancy behind lung cancer and the sixth leading cause of cancer death in the world [1, 2]. The incidence and death of esophageal cancer in China account for about 50% of the world's cases [3]. The proportion of male and female patients dying is about 2:1, and most of them are over 40 years old [4]. The typical symptom of esophageal cancer is progressive dysphagia, due to various treatments only to prolong survival, how to improve the quality of life (QOL) of patients becomes the concerning in field of medicine. Consequently, a lot of measuring instruments such as QOL/PRO and mental health scales have been developed and are widely used in clinical practices and researches.

However, the interpretation of the scores of the scale is usually judged by the P value, more and more scholars have realized that it is not reasonable and scientific to judge the curative effect only according to the different scale scores before and after the treatments (hypothesis test P values). In fact, the P value will become statistically significant as the samples being big enough, which does not mean having clinical significance [5]. Therefore, a key question in the application of the scale is how much its score must change to be clinically meaningful, namely, the minimum clinical important difference (MCID).

There are different names and meanings for MCID: minimal important difference (MID) [6], minimal clinically important change (MCIC) [7], the smallest detectable difference (SDD), minimal detectable change (MDC) [8],

Loading [MathJax]/jax/output/CommonHTML/fonts/TeX/fontdata.js e several calculation standards with its name and

standard having not been completely unified [10–13] : deterioration, a little deterioration, no change, a little improvement, improvement, etc.. There are several methods for the formulation of MCID, among which there are two traditional methods including anchor-based methods and distribution-based methods. Although the traditional methods have their advantages, their shortcomings and limitations are gradually exposed for there is no unified standard. All anchor-based approaches described by Crosby et al. [14] are limited in that they fail to take into account the variability of the instrument and/or the sample. The major disadvantage of all methods using the distribution-based approach is that they do not, in themselves, provide a good indication of the importance of the observed change[15].

In recent years, some new methods have been proposed such as ROC curve method based on anchor and multiple linear regression model[16, 17]. This paper is aimed to discuss in detail how to apply the classical anchor-based methods, especially the new methods in recent years, to formulate MCID for the Quality of Life Measurement Scale QLICP-ES (V2.0) for Esophageal Cancer, and to compare the values of MCID under different methods and standards. Here, the QLICP-ES (V2.0) is an QOL instrument for esophageal cancer under the system of QLICPs (Quality of Life Instruments for Cancer Patients) [8, 18], forming by a generic module QLICP-GM (V2.0) (including domains of physical function, psychological function, social functions, common symptoms and side effects) and an esophageal cancer specific module. The QLICPs is a Chinese QOL instruments system developed by module approach with a general module (QLICP-GM) being used with all types of cancer, and some specific modules for different cancers[19, 20].

Methods

Survey Methods

Patients with esophageal cancer who agreed to participate in this study and satisfied our inclusion criteria were investigated in Yunnan tumor hospital and cancer prevention center of Sun Yat-Sen University. The investigators (doctors/ nurses/medical postgraduates) explained the aim of the test and the scales to the patients. The Participating patients were required to finish the informed consent form and the scales of QLICP-ES (V2.0) and Chinese version of EORTC QLQ-C30 [21] independently on the day of admission to the hospital, and once again at the day before discharge.

The raw scores of items, domains and overall scale were calculated for the QLICP-ES according to the scoring guide, with each domain score being obtained by adding its own item score together and the overall score being the sum of five domains score. And all domains and the overall scores were linearly converted to a 0-100 scale standardized scores.

Anchor-based Method

The better method in formulation of MCID is anchor-based method, which was proposed by American scholar Lydick et al. [22] in 1993. Its principle is to clarify the meaning of the rating change of the scale by examining the relationship between the scale and the score of another independent measurement tool or other indicators. First, an appropriate anchor was selected and the correlation coefficient between the anchor and

the test scale was reported. Revicki [12] et al. believed that the correlation coefficient should be no less than 0.30 ~ 0.35. Second, MCID were calculated according to some standards defining the effects of treatments.

In this paper, the data were obtained from the self-matched experimental design, and the anchor-based method was mainly used to formulate the MCID of QLICP-ES. The 29th item of EORTC QLQ-C30, "Q29, how do you evaluate your overall health in the past week?", is used as the subjective anchor, with the answers including seven grades (from very poor to very good). Pearson correlation analysis was used to calculate the correlation coefficients between Q29 and various domains. The two effects standards of "one grade difference" and "at least one grade difference" were selected to develop MCID, ie. the same anchor scores differ one grade after the intervention (including the rise and fall of a level), at least one grade (including the rise and fall of one or more levels).

If represents respondents baseline score (on the day of admission), on behalf of the respondents rating score after intervention (the day before discharge), and then suitable patients according to two standards were selected and the difference d between two measuring points was computed. If the patient's anchor overall health improves, then $d = +$; if the patient's anchor overall health deteriorates, then $d = -$. The mean of the difference of all patients selected was as the MCID.

Roc Curve Method

Both the anchor-based method and the distribution-based method have some disadvantages, therefore, Crosby et al. [14] plead for a combination of anchor-based and distribution-based methods to take advantage of both an external criterion and a measure of variability. We call this method as ROC curve method for it is on the basis of ROC curve and anchor-based MIC distribution in nature [15].

First, using an anchor, the patients were divided into two groups: one grade difference/at least one grade difference, no change. Then the distribution of the change in scores on the health status instrument was plotted.

Second, the cut-off point for an MIC was chosen. Here two cut-off points were considered: the Receiver Operating Characteristic (ROC) cut-off point and the 95% limit cut-off point. The ROC cut-off point is the value for which the sum of percentages of false positive and false negative classifications ($[1 - \text{sensitivity}] + [1 - \text{specificity}]$) is smallest. The 95% limit cut-off point is based on the distribution of scores of these persons who are unchanged according to the anchor.

Next, using the 95% limit cut-off point, MIC for improvement is defined as the 95% upper limit of the distribution of scores of these persons who are unchanged according to the anchor $[\text{mean change} + 1.645 \text{SD}_{\text{change}}]$. Note that the 95% limit cut-off point corresponds with 95% specificity on the ROC curve.

To determine the ROC cut-off point for each change in domain score, the sensitivity and specificity were calculated. To construct the ROC curve, the combination of sensitivity and 1-specificity for each change in domain scores was plotted. The MIC, defined as the optimal cut-off point, is found on the ROC curve at the

point closest to the upper-left corner (i.e. where the sum of the percentages of misclassified patients is lowest).

Multiple Linear Regression Models

Angst et al. [23] in 2017 has put forward a MCID method by multiple linear regression model, with its advantage adjusting the potential confounding factors. The specific steps are as follows:

First, variables analyzed were determined by anchor options and also potential influence factors. The score change after treatments "" was used as the dependent variable, and the classification group by anchor adopting two kinds of standards "one grade difference" and "at least one grade difference", and potential influence factors such as gender, age, level of education, family economic etc. were used as independent variables.

Second, multivariate linear regression models were built and the parameters and the predictive value of the mean were estimated by SPSS. The multivariate linear regression model was $y = a_0 + a_1x_1 + a_2x_2 + \dots + a_kx_k$. Where $x_1, x_2, x_3, x_4, x_5, x_6$ represents gender, age, level of education, family economic, category, baseline points, respectively, and $a_1, a_2, \dots, a_6$ is the partial regression coefficient of with $x_1, x_2, x_3, x_4, x_5, x_6$, respectively.

After $a_1, a_2, \dots, a_6$ estimated, the predictive value of the mean (ie. MCID) can be calculated, and also its 95% confidence interval can be estimated.

Based on the empirical comparison of two different criteria and these anchor methods of ROC curve and multiple linear regression model, a reasonable calculation of MCID for the esophageal cancer scale (QLICP-ES) was carried out.

Results

Socio-demographic characteristics of the sample

The total sample included 232 cases of hospitalized patients with esophageal cancer aged 35 years to 82 years (median age = 60 years and mean age = 59.3 ± 8.9 years). 204 (87.9%) were male and 203 (87.5%) were of Han ethnicity. 139 (59.9%) have a fair perceived income. On education level, 81 cases (34.9%) finished primary school, while 129 (55.6%) completed high school, and 22 (9.5%) had a college or post-graduate degree.

220 patients (94.8%) completed the questionnaires at discharge (about four weeks follow-up) and the data were used for computing score change for each patient.

Correlation Coefficients Of Q29 With Domains Of The Qlicp-es

According to Pearson correlation analysis, the correlation coefficients of Q29 and other domains were all Loading [MathJax]/jax/output/CommonHTML/fonts/TeX/fontdata.js 1 in detail), except for the correlation coefficients of

Q29 and psychological function of 0.17. In other words, Q29 could be used as a subjective anchor to calculate the MCID in all domains of the esophageal cancer scale.

Table 1
Correlation coefficients between Q29 and domains of the QLICP-ES

Item	PHD	PSD	SOD	SSD	SPD	CGM	TOT
Q29	0.69**	0.17*	0.32**	0.56**	0.68**	0.68**	0.75**
Note: *: $P \leq 0.05$; **: $P \leq 0.01$; Physical domain –PHD, Psychological domain-PSD, Social domain-SOD, Common symptoms and side effect domain-SSD, Core/general module-CGM, Specific domain-SPD, Total-TOT.							

Mcid By Anchor-based Method

When Q29 was taken as the subjective anchor, 55 patients had no change in anchor option after interventions, 102 patients had a change with difference of one grade, and 165 patients had a change with difference of at least one grade. As can be seen from Table 2, the mean score changes are positive except of psychological function, and the MCID value obtained by the standard of "at least one grade difference" (standard B) is larger than that obtained by the standard of "one grade difference" (standard A). No matter standards, the MCID value of physiological function was larger than that of the other domains, ranging from 4 to 10.

Table 2
The MCID of QLICP-ES (V2.0) determined by anchor-based method ($n_A=102$, $n_B=165$)

Domain	Items	Standard A $\bar{x} \pm s$	Standard B $\bar{x} \pm s$	Standard A MCID	Standard B MCID
Physical domain (PHD)	8	15.1 ± 14.8	19.3 ± 16.1	15.1	19.3
Psychological domain (PSD)	9	-4.4 ± 11.8	-4.2 ± 12.4	4.4	4.2
Social domain (SOD)	8	3.1 ± 10.2	4.8 ± 11.2	3.1	4.8
Common symptoms and side effect domain (SSD)	7	6.7 ± 10.7	7.7 ± 11.3	6.7	7.7
Core/general module (CGM)	32	4.8 ± 6.5	6.5 ± 7.3	4.8	6.5
Specific domain (SPD)	16	8.5 ± 8.3	9.5 ± 9.2	8.5	9.5
Total (TOT)	48	6.0 ± 6.0	7.5 ± 6.8	6.0	7.5

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Mcid By Roc Curve Method

The sample size of ROC curve method is different from that of the anchor-based method, which includes patients who had no change in anchor option after interventions. Therefore, in the ROC curve method, the sample size of standard A is 157, and that of standard B is 220. The area under ROC curve (AUC) and MCID values of all domains of the QLICP-ES in each standard are shown in Table 3, Fig. 1 and Fig. 2, with Fig. 1 and Fig. 2 showing the ROC curves of each domain for standard A and standard B, respectively. As can be seen from Table 3, the MCID values obtained by ROC curve method are consistent and relatively stable under the two standards, except for the psychological function and the specific module, the MCID values.

Table 3
The MCID of QLICP-ES (V2.0) determined by ROC curves ($n_A=157$, $n_B=220$)

Domain	Standard A AUC	Standard B AUC	Standard A MCID	Standard B MCID
Physical domain (PHD)	0.82	0.86	7.8	7.8
Psychological domain (PSD)	0.41	0.41	9.7	5.6
Social domain (SOD)	0.69	0.72	4.7	4.7
Common symptoms and side effect domain (SSD)	0.71	0.73	3.6	3.6
Core/general module (CGM)	0.79	0.83	4.3	4.3
Specific domain (SPD)	0.76	0.78	2.3	7.0
Total (TOT)	0.81	0.83	2.9	2.9

Mcid By Multiple Linear Regression Models

Table 4 presented the MCID values and regression models for different domains of the scale in standard A, as well as the P values and R^2 of the models. Among them, the assignment of variables is as follows: the score difference between two measuring points, x_1 : gender(male = 0, female = 1), x_2 : age($\leq 60 = 0$, $> 60 = 1$), x_3 : education(Primary = 1, middle = 2, high or technical secondary school = 3, junior college = 4, bachelor degree or above = 5), x_4 : family economy(poor = 1, medium = 2, rich = 3), x_5 : group(no change = 0, Change a level = 1), x_6 : baseline score of domains. The assignment of variables in Standard B is almost the same as standard A except for x_5 : group (no change = 0, change by more than one level = 1).

Table 4
The MCID of QLICP-ES (V2.0) determined by Multiple linear regression in standard A ($n_A=157$)

Domain	MCID	P	R^2	Multiple linear regression model
PHD	9.0	< 0.001	0.27	$= -15.46 - 2.81x_1 + 1.01x_2 - 1.21x_3 + 4.05x_4 + 16.37x_5 + 0.13x_6$
PSD	3.0	0.027	0.05	$= -5.60 + 3.24x_1 - 0.14x_2 + 0.67x_3 - 2.86x_4 - 2.51x_5 + 0.12x_6$
SOD	1.2	< 0.001	0.12	$= 3.72 - 1.36x_1 - 0.61x_2 - 0.25x_3 + 3.81x_4 + 4.42x_5 - 0.17x_6$
SSD	4.0	< 0.001	0.22	$= 24.16 + 3.24x_1 - 1.13x_2 - 0.62x_3 - 0.06x_4 + 6.65x_5 - 0.29x_6$
CGM	2.6	< 0.001	0.22	$= 9.07 + 0.90x_1 + 0.08x_2 - 0.28x_3 + 1.53x_4 + 5.38x_5 - 0.18x_6$
SPD	5.9	< 0.001	0.12	$= 3.13 + 1.26x_1 + 0.50x_2 - 0.35x_3 + 0.90x_4 + 7.23x_5 - 0.04x_6$
TOT	3.7	< 0.001	0.22	$= 3.86 + 0.93x_1 + 0.27x_2 - 0.33x_3 + 1.13x_4 + 6.23x_5 - 0.08x_6$
Note:: The score difference between two measuring points, x_1 : gender (male = 0, female = 1), x_2 : age (≤ 60 = 0, > 60 = 1), x_3 : education (Primary = 1, middle = 2, high or technical secondary school = 3, junior college = 4, bachelor degree or above = 5), x_4 : family economy (poor = 1, medium = 2, rich = 3), x_5 : group (no change = 0, Change a level = 1), x_6 : Field base points. Physical domain – PHD, Psychological domain-PSD, Social domain-SOD, Common symptoms and side effect domain-SSD, Core/general module-CGM, Specific domain-SPD, Total-TOT.				

Table 5 presented the MCID values and regression models for different domains of the scale in standard B, as well as the P values and R^2 of the models. It can be seen that the MCID value obtained by this method is similar to that of the traditional anchor method. Moreover, the MCID value obtained by standard B is larger than that obtained by standard A.

Table 5
The MCID of QLICP-ES (V2.0) determined by Multiple linear regression in standard B (n_B=220)

Domain	MCID	<i>P</i>	<i>R</i> ²	Multiple linear regression model
PHD	13.9	< 0.001	0.36	= -26.36 - 0.03x ₁ - 0.73x ₂ - 0.38x ₃ + 1.62x ₄ + 19.76x ₅ + 0.35x ₆
PSD	3.3	0.002	0.07	= -13.37 + 0.08x ₁ + 0.22x ₂ + 0.63x ₃ - 2.10x ₄ - 1.72x ₅ + 0.21x ₆
SOD	3.0	0.002	0.07	= -7.83 + 0.71x ₁ - 0.66x ₂ - 0.46x ₃ + 1.45x ₄ + 6.53x ₅ + 0.06x ₆
SSD	5.6	< 0.001	0.13	= 15.90 + 1.39x ₁ - 0.48x ₂ + 0.20x ₃ - 0.79x ₄ + 8.57x ₅ + 0.20x ₆
CGM	4.5	< 0.001	0.18	= 1.53 + 1.07x ₁ - 0.63x ₂ + 0.08x ₃ + 0.50x ₄ + 7.72x ₅ - 0.05x ₆
SPD	7.4	< 0.001	0.12	= -2.42 + 0.79x ₁ + 0.18x ₂ - 0.26x ₃ + 0.43x ₄ + 7.92x ₅ + 0.04x ₆
TOT	5.5	< 0.001	0.21	= -1.25 + 0.98x ₁ - 0.33x ₂ - 0.05x ₃ + 0.43x ₄ + 7.91x ₅ + 0.01x ₆
Note:: The score difference between two measuring points, x ₁ : gender (male = 0, female = 1), x ₂ : age (≤ 60 = 0, > 60 = 1), x ₃ : education (Primary = 1, middle = 2, high or technical secondary school = 3, junior college = 4, bachelor degree or above = 5), x ₄ : family economy (poor = 1, medium = 2, rich = 3), x ₅ : group (no change = 0, Change by more than one level = 1), x ₆ : Field base points. Physical domain - PHD, Psychological domain - PSD, Social domain - SOD, Common symptoms and side effect domain - SSD, Core/general module - CGM, Specific domain - SPD, Total - TOT.				

Discussions

Currently, there is no international gold standard for the formulation of MCID, anchor-based and distribution-based methods are often used for development of MCID. Relevant literature [24–26] points out that MCID calculated by anchoring should be taken as the main method. Xu et al. [27] obtained the weighted MCID of anchor method, ES method in distribution method or two methods through SPSS simulation. In the anchor-based method, internationally recognized comprehensive scales such as SF-36 and St. George's Breathing Questionnaire (SGRQ) are commonly used as anchors. It can also be seen that the mean values of the two anchors were selected as MCID [28].

In this study, anchor-based method, ROC curve method and the multiple linear regression models were used for both two standards, providing a basis for selecting the appropriate MCID.

First of all, the correlation coefficients between Q29 and various domains are mostly higher than 0.30, showing a strong correlation. Therefore, Q29 can be used as a subjective anchor.

In terms of the two standards, the MCID obtained from standard B is slightly larger than that from standard A, but standard A "one grade difference" can reflect the minimum clinical difference directly. In terms of the three methods, MCID value ranked as follows: anchor-based > ROC curve > multiple linear regression model, and the two standards of ROC curve method produced almost the same MCID.

Anchor-based method is a traditional and widely used method, which can verify the significance of changes in feelings [29]. However, it also has many problems,

such as determination of suitable anchor, calculation of the difference between positive and negative values, selection of mean and median according to scores distributions, the appropriateness of using clinical objective indicators as objective anchors, and so on [30, 31].

The ROC curve method integrates the anchor-based method and the distribution-based method. The area under the ROC curve shows the rationality of the selected anchors, the AUC of this study is basically above 0.7, indicating a good effect. The MIC corresponding sensitivity and specificity are visualized, increasing the precision and accuracy of the MID estimation. The ROC approach integrates type-one and type-two errors and lie within reasonable limits, and it is suitable for data that is not normally distributed [32, 33]. But the MIC_{ROC} is very sensitive to random sampling variation, especially in relatively small samples, and the whole queue data is not used. It is difficult to identify the cut-off point with the best sensitivity and specificity at one glance in the ROC curve. Therefore, Terluin [34] introduced an alternative to the ROC-based MIC, based on predictive modeling.

Multiple linear regression model as an extension of the average change method, opens a new field of vision. R^2 in this study was lower, possibly because some independent variables had little effect on dependent variables although the model was significant with all P values being less than 0.05. It's less bias for adjustment or control the MCID of confounding factors. Furthermore, this model can be extended by covariables that may causes confusion and may not be equally distributed between the transition categories, for example, sex, age[23].

The similarity between the multiple linear regression model and the ROC curve method is that the sample sizes of standard A and B are the same. The difference is that multiple linear regression models use basic patient information and can generate 95% confidence intervals to predict the individual mean and the population mean, while the ROC curve method can increase the precision and accuracy of the MCID estimation.

All methods using anchors to calculate MCID have some similarities and highlights. The advantage is that anchors can be used to give professional explanations, while the disadvantage is that it is difficult to find suitable anchors, and there may be some differences between values produced by different anchors, and the measurement error is ignored [35]. Besides, the traditional anchor-based method is simple and widely used, the ROC curve method is relatively stable, and the multiple regression model can control confounding factors. Therefore, different standards and methods should be selected according to the research purpose and sample characteristics.

In addition to the above methods, some other methods are gradually studied and used, such as Logistic regression model, response cumulative distribution function and so on. They can be also used to calculate MCID for the scale of QLICP-ES in the future.

To sum up, the different methods produce different MCID values. A lot of different MCID values were presented so that it can be easy and convenient to select by users in this paper. Despite all this, in consideration of compromise and stability, the recommended MCID values of physical domain, psychological domain, social domain, common symptom and side-effects domain, the specific domain and the overall were

7.8, 9.7, 4.7, 3.6, 4.3, 2.3 and 2.9, respectively. Obviously, it was calculated according to ROC curve method under standard A.

Conclusions

Different methods have their own advantages and disadvantages, and also different definitions and standards can be adopted according to research purposes and methods. In this paper, a lot of different MCID values were presented so that it can be easy and convenient to select by users. The purpose of this study is to provide the basis for selecting the appropriate MCID formulation method. As a hot and difficult problem, MCID needs to be studied further.

Declarations

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Availability of data and materials

Not applicable.

Authors' contributions

CHW, GFL designed the study. DDR, TW, YBQ, JDZ and JYF performed the data collection. DDR, TW performed data analyses and drafted the manuscript. CHW revised the manuscript deeply. All authors contributed to interpreting the data, and have read and approved the final manuscript.

Ethics approval and consent to participate

The study protocol and the informed consent form were approved by the IRB (institutional review board) of the affiliated hospital of Guangdong Medical University (PJ2012052, YJYS2019010). The respondents were voluntary and provided written consent for participation.

Consent for publication

Competing interests

The authors declare that they have no competing interests.

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Figures

由结生成的对角线段。

Figure 1

ROC curve of the group with no change and the group with change of at least one grade difference

由结生成的对角线段。

Figure 2

ROC curves of the group with no change and the group with change of one grade difference