• Investigation •

# Responsiveness and minimal clinically important difference of the Chinese version of the Low Vision Quality of Life Questionnaire after cataract surgery

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Received: 2017-10-23 Accepted: 2018-11-28

## Abstract

**• AIM: To investigate the Chinese version of the Low Vision Quality of Life Questionnaire (CLVQOL) as an instrument for obtaining clinically important changes after cataract surgery.**

**• METHODS: Patients underwent cataract surgery in Shanghai General Hospital, Shanghai Jiao Tong University, who fit the inclusion criteria were recruited. Two CLVQOLs were administered, including a preoperative CLVQOL and a CLVQOL at the end of the 3mo follow-up period, and were completed using face-to-face interviews or phone interviews conducted by trained investigators. The minimal clinically important difference (MCID) was calculated using an anchor-based method and a distribution method. In addition, the responsiveness of the questionnaire was measured.**

**• RESULTS: A total of 155 residents were enrolled. The average visual acuity (VA) preoperatively was 0.08 (SD=0.05), and it increased to 0.47 (SD=0.28) at the end of follow-up. Statistically significant positive changes in the CLVQOL scores indicated significant improvement of vision related quality of life after cataract surgery. With the larger value between the two results as the final value, the MCID values of the CLVQOL (scores of the four scales as well as the total score) were 8.94, 2.61, 4.34, 3.10 and 17.63, respectively. The CLVQOL has both good internal and external responsiveness.**

**• CONCLUSION: CLVQOL scores are appropriate instruments for obtaining clinically important changes after cataract surgery. This study is an effective exploration for establishing cataract surgery efficacy standards, which helps clinical and scientific research workers in ophthalmology to gain a more in-depth understanding when using CLVQOL.**

**• KEYWORDS:** responsiveness; minimal clinically important difference; Chinese Version of the Low Vision Quality of Life Questionnaire; Chinese

**DOI:10.18240/ijo.2019.03.23**

**Citation:** Xue WW, Zhang P, Zou HD. Responsiveness and minimal clinically important difference of the Chinese version of the Low Vision Quality of Life Questionnaire after cataract surgery. *Int J Ophthalmol* 2019;12(3):504-509

## INTRODUCTION

According to a report by the WHO, 285 million people suffered from visual impairment in 2010, including 246 million people with low vision and 39 million people with blindness. Ninety percent of people with low vision live in low and middle-income countries[1]. Visual impairment not only creates economic and psychological burdens for these individuals and their families but also directly affects their work and life abilities. It is believed that the visual acuity (VA) indicator that is widely used clinically does not fully reflect the overall impact of eye diseases on the sufferer or the effect of interventions; therefore, vision-related quality of life (VRQOL) needs to be evaluated[2]. In recent years, VRQOL scales and questionnaires have been widely used in clinical and scientific research work. Wolffsohn and Cochrane[3] developed the Low Vision Quality of Life Questionnaire (LVQOL) in 2000. The LVQOL is a questionnaire that is specifically used for the evaluation of people with low vision and VRQOL[3-4]. In 2002, Zou *et al*[5] translated the LVQOL into Chinese, and together with back-translation and cultural adjustment, they established the Chinese version of the Low Vision Quality of Life Questionnaire (CLVQOL). So far, the CLVQOL has been applied in the VRQOL assessment of people with visual impairment due to cataracts, age-related macular degeneration, retinal detachment and other diseases; these applications have confirmed that the CLVQOL has good reliability and validity and can be used to measure the VRQOL of Chinese people with various types of low vision[6-13].

In clinical practice, a curative effect is often evaluated by assessing the change after an intervention and whether there is statistical significance in the difference between the intervention group and control group. However, statistical significance is unable to reflect the presence of the "clinical significance" in this change or difference[14]. In this context, Jaeschke *et al*[15] proposed the concept of the minimal clinically important difference (MCID). From the perspective of the patient, the MCID refers to "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management". The MCID can be used as the threshold of clinical significance for a score change between before and after the intervention and can be used to evaluate whether the change in an outcome indicator is true or has clinical significance in a prospective study or an outcome study[16].

In addition, the MCID can also be used to assess the effectiveness of the Quality of Life Questionnaire. The Quality of Life Questionnaire is a subjective evaluation. Therefore, the evaluation of the questionnaire results by a physician may have errors due to subjective factors. In contrast, the MCID can represent the value of the minimum change in questionnaire scores accepted by patients, from the perspective of the patient or the physician, regardless of the side effects and cost. The evaluation result is less influenced by subjective factors and thus can better explain the clinical significance of score changes or differences of the evaluation tool (*i.e.* scales or questionnaires) as well as the change value of certain objective indicators before and after an intervention[17]. Researchers in China and other countries have conducted many studies and have held many discussions regarding the MCID algorithm and its significance and have estimated the MCID value of many questionnaires[18-20]. However, in the field of eye disease research, it is rare to use MCID analysis in Quality of Life Questionnaire studies. One example is a dry eye study in which Miller *et al*[21] studied the MCID of the Ocular Surface Disease Index (OSDI) in the evaluation of patients with dry eye. And for a special scale for the assessment of visual damage, Bilbao *et al*[22] have calculated a recommended MCID value of cataract patients for VF-14 in a past study. After the MCID was established, it was used to determine the optimal timing of surgery for cataract patients[23] and the relationship between social demographic characteristics and outcomes after surgery in cataract patients[24]. In addition, it is of great help for clinicians to explain the outcome after surgery to patients with cataracts.

In this study, we assessed the change in life quality after surgery in cataract patients by calculating the MCID values of the CLVQOL to provide a basis for scientific evaluation and interpretation in an exploration of a special VRQOL scale of visual function damage. It is reported as follows.

## SUBJECTS AND METHODS

**Ethical Apporval** The Institutional Review Board of the Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China, approved the study. The study adhered to the tenets of the Declaration of Helsinki and all the laws of the authors' home country. Parents/legal guardians of the study subjects gave informed consent for participation in this study.

This was a prospective, observational study. The data collection period was between January 2014 and December 2015. The study subjects were cataract surgery patients in Shanghai General Hospital, Shanghai Jiao Tong University. For the cataract surgery, standard microscopic phacoemulsification was combined with implantation of a foldable intraocular lens. Cortical hormone and antibiotic eye drops were used postoperatively for a short time. The inclusion criteria for the study were that the patient had cataract surgery in one eye, that the other eye had never undergone cataract surgery and that the patient agreed to participate in the research study and follow-up. The exclusion criteria for the study were as follows: the patient suffered from other ocular diseases that seriously affect visual function (*e.g.* amblyopia, glaucoma, diabetic retinopathy, severe age-related macular degeneration, retinal detachment, high myopia); the patient had intraoperative complications or postoperative complications from cataract surgery; the patient had other eye surgery combined with cataract surgery; or the eyes underwent any surgery during the follow-up period.

In this study, we used the CLVQOL to measure the VRQOL of research subjects. The CLVQOL has 25 items with 4 scales: namely, 1) distance vision, mobility and light perception; 2) adjustment ability; 3) ability to read and perform fine work; and 4) daily life ability. All 25 items related only to vision loss (including blindness and low vision) that are scored from 0 to 5, with a total possible score of 125 points (*i.e.* the higher the score, the higher the quality of life)[5]. According to the assessment results of community residents and clinical patients in Shanghai, both the reliability and validity of the CLVQOL are good; the questionnaire is considered to be in accordance with the characteristics of Chinese culture and can sensitively reflect the VRQOL status of people with vision loss[5]. In this study, the patients voluntarily filled out the questionnaire. The CLVQOL was administered twice on each participant, first preoperatively and at the end of the 3mo follow-up period, and was completed using face-to-face interviews or phone interviews conducted by trained investigators. The questionnaire scores were calculated as the VRQOL data of the subjects.

In this study, the baseline of four scales of the CLVQOL and the ceiling effect at the end of the follow-up period were calculated to evaluate the resolution capability of the questionnaire, namely, the percentage of subjects who scored the highest possible dimension score[25]. In addition, the responsiveness of the questionnaire was measured to investigate whether the differences between the total points and points of each scale before and after surgery were statistically significant using a paired *t* test. If *P* was less than 0.01, the questionnaire was considered to have good internal responsiveness. For external responsiveness, the self-assessed health status changes of the patients were selected as an external standard and the correlations between the questionnaire score and the self-assessed status score were investigated and analyzed. A value of the correlation coefficient that was closer to one indicated a stronger correlation[26].

The MCID was calculated using an anchor-based method and a distribution method. At the end of the 3mo follow-up period, all patients were asked to answer the following transitional question with the self-assessed health status change of the patient after cataract surgery: "Compared to the condition before the surgery, how do you evaluate your health now?" The possible answers were: 1) much worse; 2) a little worse; 3) about the same; 4) a little better; 5) much better. In this study, which had a longitudinal design, the MCID was estimated for CLVQOL, by the mean change score for patients whose response to the transitional question was "a little better"[27]. The distribution method was as follows: the effect size (ES) of the CLVQOL was calculated and 0.5ES was considered to be the estimated value of MCID[28], according to the equation: $ES=\frac{x_1-x_0}{\sqrt{\frac{\Sigma(x_0-\bar{x}_0)^2}{n-1}}}$. $X_0$ was the mean of the preoperative scores; $X_1$ was the mean of the postoperative scores; and *n* was the sample size[29].

## RESULTS

Of the 155 cataract patients in this study, there were 71 men (45.81%) and 84 women (54.19%). The age range of the patients was 45 to 97y, with an average age of 65.98±10.82y. There were 35 patients younger than 50y (22.58%), 71 patients aged 50 to 69y (45.81%), and 49 patients of age 70 years or older (31.61%). There were no serious complications during surgery. Intraocular lens were all implanted on schedule. A Snellen chart was used to examine the patients' distance VA. The average preoperative VA was 0.08 (SD=0.05), and the average postoperative VA of the eye that underwent surgery eye was 0.47 (SD=0.28) at the end of the follow-up period. The changes in vision and the CLVQOL scores before and after surgery are shown in Table 1. For the four scales of CLVQOL, there were no significant ceiling effects before surgery (16.8%, 0.6%, 16.8% and 16.8%). However, significant ceiling effects were observed postoperatively at the end of the follow-up period (23.2%, 26.5%, 27.1% and 41.9%, respectively).

**Table 1 Vision and CLVQOL changes in patients undergoing cataract surgery** mean (SD)

| Items | Before surgery | After surgery | Change | *P* |
|---|---|---|---|---|
| VA | 0.08 (0.05) | 0.47 (0.28) | 0.39 (0.26) | <0.001 |
| CLVQOL | | | | |
| Scale 1 | 31.80 (8.23) | 50.75 (9.49) | 18.95 (12.61) | <0.001 |
| Scale 2 | 8.57 (2.46) | 16.04 (3.72) | 7.47 (4.45) | <0.001 |
| Scale 3 | 13.79 (6.30) | 19.31 (5.17) | 5.52 (8.24) | <0.001 |
| Scale 4 | 13.25 (4.87) | 16.78 (4.23) | 3.53 (6.31) | <0.001 |
| Total | 67.41 (18.53) | 102.88 (20.96) | 35.47 (28.34) | <0.001 |

Scale 1: Distance vision, mobility and light perception; Scale 2: Adjustment ability; Scale 3: Ability to read and perform fine work; Scale 4: Daily life ability.

When investigating the changes of scores in the four scales and the total score of CLVQOL before and after surgery using a paired *t* test, we found that the *P* values were all less than 0.001 and that the postoperative scores were all higher than the preoperative scores (Table 1). These findings indicate that the score change of the questionnaire before and after surgery were statistically significant, with good internal responsiveness. The correlation coefficient between the scores of the four scales and the total score of CLVQOL and self-assessment scores after surgery were 0.671, 0.646, 0.679, 0.724 and 0.732, respectively. These findings indicate that the questionnaire scores were highly correlated with the self-assessment scores and showed that the questionnaire had good external responsiveness.

With the self-assessed health status changes of the patients before and after surgery as the anchor, of the 155 patients undergoing cataract surgery, 15 patients selected "1" (much worse), 21 patients selected "2" (a little worse), 30 patients selected "3" (about the same), 51 patients selected "4" (a little better), and 38 patients selected "5" (much better).

The MCID values of the CLVQOL calculated with the anchor-based method and the distribution method are shown in Table 2. With the larger value between the two results as the final value[30], the MCID values of the CLVQOL (scores of the four scales including a, b, c and d as well as the total score) were 8.94, 2.61, 4.34, 3.10 and 17.63, respectively. In other words, if the CLVQOL value (scores of the four scales including scale 1, 2, 3, and 4 as well as the total score) changes before and after cataract surgery were larger than 8.94, 2.61, 4.34, 3.10 and 17.63, respectively, then the improvement of the quality of life related to vision in patients undergoing cataract surgery was of clinical significance and was not affected by

**Table 2 MCID value of CLVQOL in 155 patients undergoing cataract surgery**

| Scales | Distribution method (0.5ES) | Anchor-based method |
|---|---|---|
| Scale 1 | 3.77 | 8.94 |
| Scale 2 | 2.61 | 1.25 |
| Scale 3 | 1.24 | 4.34 |
| Scale 4 | 0.92 | 3.10 |
| Total | 4.82 | 17.63 |

Scale 1: Distance vision, mobility and light perception; Scale 2: Adjustment ability; Scale 3: Abilities of reading and meticulous work; Scale 4: Daily life ability.

random error; otherwise, the improvement of the quality of life related to vision in patients undergoing cataract surgery may not really exist or may be too small to be felt by patients.

## DISCUSSION

Since its establishment, the LVQOL has been translated into Chinese, Indian, Thai and other languages[5,31-32]. With its application in the assessment of the VRQOL in low vision patients, issues such as the interpretation of the questionnaire score and the way to explain the change in scores before and after intervention are becoming more and more important. The MCID values of CLVQOL also have reference significance for the interpretation of the LVQOL in other languages.

The ceiling effect means that the scores of a significant number of subjects are centrally distributed on the higher side, which reflects the important characteristics of the score distribution. A proportion of greater than 15% is considered to be statistically significant[33]. In our study, the ceiling effects of the preoperative scores of the four scales and the total score of CLVQOL are not statistically significant, indicating reasonable item design. However, postoperatively, the four scales show a strong ceiling effect, among which the first three scales all have ceiling effects of less than 30%, which is acceptable; however, the fourth scale has a ceiling effect of 41.9%, which leads to the validity decline of the questionnaire, indicating that the questionnaire items still need further improvement. Responsiveness refers to the ability of the questionnaire to measure the subjects' significant subtle changes and reflects the ability of quality of life to change over time[26]. It is considered to be one aspect of a validity check of the questionnaire[34]. Good responsiveness is the precondition of calculating MCID[27]. According to the calculation results, the CLVQOL has both good internal responsiveness and good external responsiveness. Responsiveness is investigated according to the group level, while MCID refers to the minimum value of scores changes of individuals with clinical significance before and after the intervention. Based on the follow-up study of the 155 cataract patients, this study determined the MCID value of CLVQOL for the first time and recommends it as the threshold value to determine whether the interventions are effective. Cataract patients were chosen as the research subject for three reasons, as follows: 1) As a common age-related disease, cataract is still the main cause of visual impairment of senior citizens, with numerous sufferers. 2) Most patients have significantly improved vision after cataract surgery, but some patients are not satisfied with their improvement; sometimes, the examined VA is inconsistent with the patient's subjective visual impairment, which poses the need for introducing the visual function questionnaire as a supplement to traditional evaluation methods. 3) Bilbao *et al*[22] have studied 4356 patients with cataracts and recommended a MCID of 15.57 for the VF-14 Questionnaire, and the comparison of MCID values of the same disease calculated through different questionnaires is more conducive to the explanation of disease and methodology.

Currently, there are a total of four estimation methods for MCID: the anchor-based method, distribution method, expert opinion method and literature analysis method. Health-related quality of life (HRQOL) is an important outcome of patients; patients should play a major role in judging whether the difference in important. The expert opinion method is to determine the MCID value completely according to the opinions of the experts and thus cannot well reflect the views of patients[35]. Brozek *et al*[36] believe that when trying to determine the MCID with patient experience as the core, this method can only play a supplementary role and has no accurate data. The literature analysis method is a method to determine the MCID through Meta, which relies on the existing literature and can only act as an auxiliary method to determine the MCID value[37]. The anchor-based method is a method to determine the MCID value based on the external anchor (subjective anchor and/or objective anchor)[38].

The anchor works with two conditions. 1) It is interpretable professionally. 2) The linear correlation coefficient between the anchor and the quality of life or clinical effects is no less than 0.30 to 0.35[36-37]. However, the anchor-based method still has obvious shortcomings. Different anchors will produce different MCIDs, and no measurement error is considered[36,39]. The distribution method considers the error of measurement and is equipped with clear calculation formulas[39]. However, different samples may produce different results and cannot provide a professional explanation of the produced MCID. In conclusion, some problems still exist in MCID research. Although there are many estimation methods that are not up to standard, there is still no "gold standard" method. Therefore, we combined two methods to calculate the MCID value of CLVQOL. From the perspective of patients, the main method that we used is considering the self-assessed health status of the patients as the anchor. For the transitional question, 32.9% (51) of patients chose 4 (a little better); 24.52% (38) of the patients chose 5 (much better).

The proportion that chose 4 (a little better) is relatively high, which improves the credibility of the MCID value to a certain extent. However, we should still pay attention to the intrinsic defect of the MCID value, which cannot be taken as an absolute threshold[27]. Compared with the results of VF-14[22], we discovered that both the MCID values account for approximately 15% of the total score (the proportion of CLVQOL is 14.10% and that of VF-14 is 15.57%).

There are still many shortcomings in this study. First, the results of the two estimation methods are not highly consistent, which can also be found in studies from other disciplines[40]. There are no "gold standard" MCID estimation methods. The two estimation methods partially overlap. Therefore, we should combine the two estimation methods and consider the anchor-based method as the main method from the perspective of patients. Second, the questionnaire is designed to comprehensively assess the quality of life related to vision of patients with low vision, but we only studied cataract patients. Therefore, the results may not be generalizable to other patients with low vision and further research is still needed.

In summary, in our study, we adopted two different methods to calculate the MCID values of the CLVQOL. This study is an effective exploration to establish cataract surgery efficacy standards, which will help clinical and scientific research workers in ophthalmology gain a more in-depth understanding when using CLVQOL and thus provides a higher application value. In addition, it is important to calculate the MCID values of other LVQOL in other versions or in other low-vision diseases.

**ACKNOWLEDGEMENTS**

**Conflicts of Interest: Xue WW,** None; **Zhang P,** None; **Zou HD,** None.

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