

Reliability and validity of the Chinese CECA10 questionnaire for Chinese patients with condyloma acuminata

Xinying Guo, MSN^a, Xinjuan Wu, MSN^{a,*}, Aimin Guo, PhD^{b,*}, Yanwei Zhao^a

Abstract

Condyloma acuminata (CA) is a sexually transmitted disease that affects quality of life (QOL). CECA10 is an English-language questionnaire for assessing QOL in patients with CA, but there is no equivalent in China. This study aimed to develop a validated and reliable Chinese version of CECA10.

The Chinese CECA10 was developed from the English version by forward translation, back translation, comparison with the original, cultural adjustments, and a pre-test (5 patients). The Chinese CECA10 and EuroQol Five Dimensions Three Level Questionnaire (EQ-5D-3L) was administered to patients with CA. Content validity (item/scale content validity indexes, I-CVI/S-CVI), test-retest reliability (intraclass coefficient, ICC), internal consistency (Cronbach α), criterion validity (comparison with the Dermatology Life Quality Index, DLQL, using Spearman correlation analysis), construct validity (exploratory factor analysis), and discriminant validity (between subgroups based on number of warts, number of recurrences, or number of sites involved) were assessed.

The Chinese CECA10 had good test-retest reliability (ICC = 0.98, $P < .001$), internal consistency (Cronbach α values of 0.88, 0.84, and 0.83 for the total questionnaire, psychological dimension, and sexual dimension, respectively), content validity (I-CVI = 1 for all items), and criterion validity ($r = -0.50$, $P < .001$). Exploratory factor analysis extracted 2 factors with a cumulative contribution of 61.75%; the factor loading with each item was >0.4 . Discriminant validity was not high. The mean CECA10 and EQ-VAS scores of 211 patients with CA (28.19 \pm 7.16 years; 139 males) were 34.56 \pm 19.01 and 64.64 \pm 19.28, respectively.

The Chinese CECA10 has good reliability and validity for evaluating the QOL of Chinese patients with CA.

Abbreviations: CA = condyloma acuminata, DLQL = Dermatology Life Quality Index, EQ-5D-3L = EuroQol Five Dimensions Three Level Questionnaire, GQOLI = General Quality of Life Inventory, HIP = HPV Impact Profile, HPV = human papillomavirus, ICC = intraclass coefficient, I-CVI = item-level content validity index, KMO = Kaiser-Meyer-Olkin, QOL = quality of life, QOL-35 = 35-item QOL instrument, S-CVI = scale-level content validity index, STDs = sexually transmitted diseases.

Keywords: CECA10 translation, condyloma acuminata, quality of life, reliability and validity

1. Introduction

Condyloma acuminata (CA), or anogenital warts, is a benign epithelial neoplasm caused by infection with human papillomavirus (HPV). CA is among the most common sexually transmitted diseases (STDs) with an annual incidence of $\sim 195/100,000$ adults^[1] and a rising incidence in China.^[2] Although therapies are

available, CA has a high recurrence rate of 40% to 60%.^[3,4] The chronic nature of CA exerts a tremendous psychological pressure on patients, which causes changes in their sexual lifestyle and a decline in their quality of life (QOL).^[5,6]

Generic QOL instruments have revealed that patients with CA have a reduced QOL.^[7-11] Generic instruments such as the General Quality of Life Inventory (GQOLI) and 35-item QOL instrument (QOL-35) have shown that the QOL of patients with CA in China is related to the frequency of CA recurrence and the patient's level of knowledge.^[12,13] One study in China used the EuroQol Five Dimensions Questionnaire (EQ-5D) to show that the QOL of patients with CA was lower than that of a national representative general population in China and that factors associated with a lower QOL were female gender, urban residency, and CA at multiple sites.^[14] Another study employed the HPV Impact Profile (HIP) to assess the QOL of women with HPV infection and found that among female patients infected with HPV, those with CA carried the most severe psychological burden and showed the greatest concern about sexual issues, which together explained most of the decline in QOL.^[15,16]

However, these generic scales are not optimized to evaluate the sexual, psychological, and emotional aspects of the QOL of patients with CA. The Quality of Life Questionnaire for Patients with Genital Warts (CECA10; CECA is the Spanish acronym for the Specific Questionnaire for Condyloma Acuminata) is an instrument that has been designed specifically for patients with

Editor: Kimon Chatzistamatou.

The authors report no conflicts of interest in this work.

Supplemental Digital Content is available for this article.

^a Nursing Department, Peking Union Medical College Hospital, ^b School of Nursing, Peking Union Medical College, Beijing, China.

* Correspondence: Xinjuan Wu, Nursing Department, Peking Union Medical College Hospital, Beijing 100730, China (e-mail: wuxinjuan@sina.com); Aimin Guo, School of Nursing, Peking Union Medical College, Beijing 100730, China (e-mail: guoaimin@hotmail.com).

Copyright © 2018 the Author(s). Published by Wolters Kluwer Health, Inc. This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

Medicine (2018) 97:9(e9917)

Received: 27 October 2017 / Received in final form: 26 January 2018 /

Accepted: 29 January 2018

<http://dx.doi.org/10.1097/MD.0000000000009917>

CA.^[17] CECA10 contains 10 items divided into 2 dimensions (6 psychological emotion items and 4 sexual activity items) and is currently available as Spanish and English versions.^[17,18] CECA10 has been reported to have good reliability and validity when applied in European patients with CA,^[18] and studies using CECA10 have found that patients with CA have a decreased QOL, show fear and anxiety toward the disease, and have concerns about sexual issues.^[11,18–20]

Unfortunately, there are no QOL questionnaires designed for Chinese patients with CA. The aims of this study were to translate the English version of CECA10 into Chinese with appropriate cultural adaptation and assess the reliability and validity of the Chinese version of CECA10 for the evaluation of QOL in Chinese patients with CA.

2. Material and methods

2.1. Patients

This was a cross-sectional validation study. Patients with CA attending the Center of Skin Diseases and Venereal Diseases of Peking Union Medical College Hospital (China) between June 2011 and December 2011 were chosen using convenience sampling. The inclusion criteria were age ≥ 18 years; a diagnosis of CA based on clinical manifestations^[3] and positive acetic acid test (perineal condyloma evident as acetowhite lesions); and (3) able to understand the questionnaire contents. The exclusion criteria were cognitive impairment or mental disorders; and refusal to participate. All patients provided informed written consent. The study was approved by the ethics committee of Peking Union Medical College Hospital.

2.2. Study design

The study design is illustrated in Fig. 1.

2.3. Questionnaires

The participants completed the following questionnaires after consultation with a doctor but before treatment initiation: demographic/clinical characteristics and Chinese versions of CECA10, EQ-5D Three Level Questionnaire (EQ-5D-3L) and Dermatology Life Quality Index (DLQI). All questionnaires were checked on-site by a researcher, and participants were asked to clarify unclear/incomplete answers. Data entry was double-checked by a second researcher.

2.3.1. Demographic and clinical characteristics. The following information was recorded by a nurse (XG) in a face-to-face interview: sex, age, income, marital status, number of sexual partners, sexual orientation, whether this was the initial diagnosis, the date of the initial diagnosis, the presence of any other STDs, the number of warts, and the sites affected.

2.3.2. Chinese version of DLQI. The DLQI includes 10 items relating to 7 dimensions (symptoms, feelings, daily activities, leisure, work and study, interpersonal relationships, and treatment).^[21] Each item is scored from 0 to 3, so the total score ranges from 0 to 30 (the higher the score, the worse the QOL). The Chinese version of the DLQI has a Cronbach α of 0.87 and a split-half reliability of 0.85.

2.3.3. Chinese version of EQ-5D-3L. EQ-5D-3L consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ-

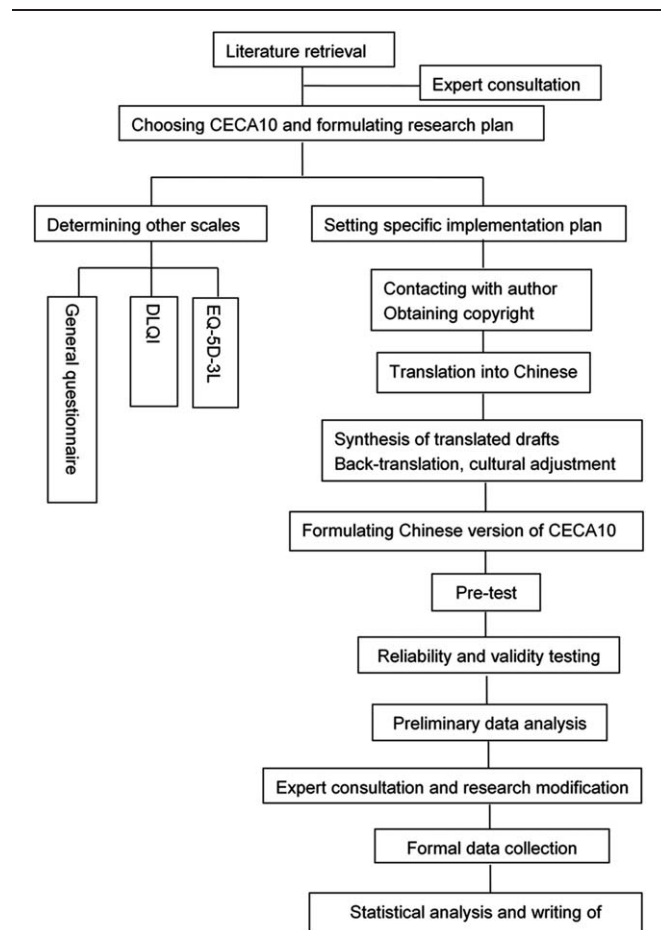


Figure 1. Technical route.

VAS), both of which were used in the present study. The former comprises 5 dimensions (mobility, self-care, daily activities, pain/discomfort, and anxiety/depression) each scored as 1 (without difficulty), 2 (with some difficulty), or 3 (with extreme difficulty). EQ-VAS uses a visual analogue scale ranging from 0 (worst imaginable health status) to 100 (best imaginable health status). The EQ-VAS score can be utilized directly, whereas the EQ-5D index is converted (using a utility value conversion table) to a QOL score ranging from 0.0 (death) to 1.0 (complete health). The Chinese version of EQ-5D has been shown to have good reliability and validity in mainland China, Taiwan, and Singapore,^[22–24] and test result equivalence between the English and Chinese versions has been demonstrated.^[25,26]

2.3.4. CECA10. CECA10^[17] is the only instrument specifically designed to evaluate the HRQL of patients with CA. CECA10 is brief, requiring only 3 to 5 minutes to administer, and readily accepted by patients. The scale contains 10 items covering a psychological dimension (6 items) and a sexual dimension (4 items), with each item scored using a Likert scale of 1 to 5. The total score ranges from 10 to 50, with a higher score indicating a better HRQL. For the Spanish version of CECA10, the psychological and sexual dimensions have Cronbach α values of 0.86 and 0.91, respectively, and test–retest reliability coefficients of 0.76 and 0.82, respectively.^[18] There is a moderate negative correlation between CECA10 and DLQI scores ($r = -0.67$, $P < .05$).^[18] The English version of CECA10 was developed

by translation and back-translation, and its reliability, validity, and equivalence to the Spanish version have been demonstrated. The English version of CECA10 has been utilized in various countries, including the UK, the Netherlands, and Finland.^[11,19,20,27]

2.4. Development of the Chinese version of CECA10

2.4.1. Research group. Each of the 8 members was responsible for a different task.

2.5. Questionnaire translation and cultural adaption

The English CECA10 was translated into Chinese independently by 2 medical professionals (XG and Meng Ouyang) familiar with its linguistic and cultural aspects. A unified version, compiled after discussions and consultation with the original author, was back-translated to English by a bilingual expert with no exposure to the original scale. To optimize the wording, 5 bilingual experts with medical backgrounds compared each item of the back-translated version with each original item, using a Likert scale (“completely consistent,” “very consistent,” “consistent,” “not very consistent,” and “inconsistent”). The revised version was back-translated to English, and the original author was consulted for suggestions.

Documents were obtained from the original author to guide patients in the completion of the questionnaire. After reviewing the results of a pre-test in 5 patients with CA, the Chinese CECA10 was finalized for reliability and validity testing.

2.5.1. Reliability and validity testing. In phase 1 testing, the item-level content validity index (I-CVI) and the scale-level content validity index (S-CVI) were measured. In phase 2 testing, the Chinese CECA10 was administered to 62 patients with CA to pre-investigate its internal consistency reliability, test-retest reliability, and criterion validity against DLQI. In phase 3 testing, CECA10 was administered to 211 patients with CA to further assess reliability and validity. To facilitate comparison with other studies, CECA10 scores were transformed to an overall percentage value (a higher value representing higher QOL), using the formula: (obtained score - minimum score) / (maximum score - minimum score) × 100. The original CECA10 scores were used for reliability and validity testing and the standardized scores for QOL evaluation.

2.5.2. Statistical analysis. A database was established using Excel (Microsoft Corp., Redmond, WA). SPSS13.0 (SPSS Inc., Chicago, IL) was used for statistical analyses. Data are presented

as the mean ± standard deviation or n (%). Test-retest reliability was measured by the intraclass coefficient (ICC), internal consistency by Cronbach α, and content validity by I-CVI and S-CVI. Exploratory factor analysis was used to assess construct validity. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett test of sphericity were used to assess the suitability of the data for factor analysis. Factor analysis was conducted using varimax orthogonal rotation, and variables with factor loading ≥0.4 were considered important. The Spearman correlation between CECA10 and DLQI scores was determined. Discriminant validity was described using analysis of variance (ANOVA; normally distributed data) or nonparametric tests (non-normally distributed data). $P < .05$ was considered statistically significant.

3. Results

3.1. Linguistic and cultural adaption of the Chinese version of CECA10

3.1.1. Synthesis of the translated versions. The 2 draft Chinese versions of CECA10 were synthesized into 1 translated document with the translators scrutinizing each other’s drafts. The translated version took into account Chinese habits, and the items were modified to be better suited to Chinese expressions.

3.1.2. Back-translation and cultural adaption. A panel of 5 experts reviewed the original (English), translated (Chinese), and back-translated (English) versions of CECA10 and concluded that the content was basically the same, except for “item 10” (Supplemental Table 1, <http://links.lww.com/MD/C122>). The back-translated version and the results of the panel review were presented to the original author, and additional modifications were made based on his suggestions (Table 1). Further revisions to the scale instructions and items were made following a pre-test in 5 patients.

3.2. Phase 1 and phase 2 testing

In phase 1 testing, all items were rated as “very relevant” or “relevant” (i.e., I-CVI=1 and S-CVI=1). Phase 2 testing in 62 patients with CA indicated that the Chinese CECA10 had good internal consistency reliability and high test-retest reliability (Supplemental Table 2–3, <http://links.lww.com/MD/C122>). Spearman correlation analysis revealed a moderate negative correlation ($r = -0.50$, $P < .001$) between the original CECA10 and DLQI.

Table 1

Adjustment of the Chinese version of CECA10 following input from the original author.

Item	Pre-adjustment	Post-adjustment
1	I am worried that my CA would never disappear	I am afraid that my disease would never disappear
2	I am anxious about whether I can recover from this infection	I am worried about whether or not my infection can be completely cured
3	I am worried about disease deterioration or the complications it would bring in the future	I am worried about disease deterioration or complications
4	I am in a bad mood at present (anxiety, depression, sorrow, uneasiness . . .)	My mood is not stable at present (anxiety, depression, sorrow, uneasiness . . .)
5	I feel more uneasy	I basically feel no sense of security
6	Being aware of the disease affects my daily life	Being aware of this disease affects my daily life
7	My libido is reduced	My libido is declined
8	I feel anxious in the process of sexual life	I feel worried when having sex
9	I avoid sexual life	I avoid sexual behavior
10	My sexual quality and/or frequency is decreased	No adjustment

Table 2
Demographic and clinical characteristics of 211 patients administered the Chinese CECA10.

Parameter	n	%
Gender		
Male	139	65.88
Female	72	34.12
Marital status		
Married	111	52.61
Unmarried	100	47.39
Sexual behavior pattern		
Heterosexual	184	87.20
Homosexual	21	9.95
Bisexual	6	2.84
History of sexually transmitted diseases		
Yes	10	4.74
No	201	95.26
Number of warts		
0	12	5.69
1–10	144	68.25
11 or more	55	26.07
Number of sites involved		
0	12	5.69
1	166	78.67
2 or more	33	15.64
Number of recurrences		
0 (new occurrence)	74	35.07
1–5	112	53.08
6 or more	25	11.85
Sexual partners during the previous six months		
1	182	86.26
2 or more	29	13.74
Education level		
Primary school or lower	2	0.95
High school	62	29.38
Junior college or higher	147	69.67
Monthly income, Yuan		
<1000	28	13.27
1000–3000 Yuan	107	50.71
3000–5000 Yuan	40	18.96
>5000 Yuan	36	17.06
Age by subgroup, y		
18–19	7	3.32
20–29	129	61.14
30–39	53	25.12
40–59	21	9.95

Table 3
Subgroup analyses to determine the discriminant validity of the Chinese CECA10.

Groups	Number of cases	Mean score	Standard deviation	F	P
Number of warts					
0	12	27.92	7.14	2.52	.08
1–10	144	23.95	7.47		
11 or more	55	22.60	7.85		
Number of recurrences					
0 (new occurrence)	74	25.22	7.56	3.12	.05
1–5	112	22.61	6.94		
6 or more	25	25.16	9.72		
Number of sites involved					
0	12	27.92	7.14	2.55	.08
1	166	23.86	7.66		
2 or more	33	22.18	7.10		

warts, recurrences, or sites involved (Table 3), suggesting that the discriminant validity of CECA10 was not high.

Construct validity was evaluated using exploratory factor analysis. The KMO statistic was 0.86 (i.e., >0.5), and the approximate Chi-squared value of Bartlett test of sphericity was 944.58 ($P < .001$), indicating that the data were suitable for factor analysis. Exploratory factor analysis extracted 2 factors with characteristic roots > 1 that were capable of explaining the majority of the statistical information presented by the CECA10 items (accumulated variance contribution of 61.75%; Table 4). The component matrix was obtained after varimax orthogonal rotation, and ordering the Chinese CECA10 items on the basis of factor loading (Table 5) showed that items 1 to 5 (psychological dimension) were dominated by common factor 1, while items 6 to 10 (sexual dimension) were dominated by common factor 2.

3.3.2. Comparison of the Chinese CECA10 and EQ-5D-3L for assessment of QOL in patients with CA. The mean CECA10 score of the 211 patients with CA was 34.56 ± 19.01 . Item 2 (“I’m worried about whether or not my infection can be completely cured”) and item 8 (“I feel worried when having sex”) ranked last in the psychological and sexual dimension, respectively (Table 6).

The mean EQ-VAS score of 64.64 ± 19.28 was significantly lower than the EQ-VAS score (80.10) in a general Chinese population ($P < .001$).^[28] Furthermore, the EQ-VAS score (and hence QOL) was significantly lower in women with CA than in men with CA (59.19 ± 20.31 versus 67.47 ± 18.16 ; $P < .001$). In the EQ-5D, the proportion of patients answering “with some

3.3. Administration of the Chinese version of CECA10 to 211 patients with CA

In phase 3 testing, the Chinese CECA10 was administered to 211 patients with CA (mean age, 28.19 ± 7.16 years; range, 18–57 years; 139 males); their demographic and clinical characteristics are summarized in Table 2.

3.3.1. Evaluation of the validity and reliability of the Chinese CECA10. The Cronbach α value was 0.88 overall, 0.84 for the psychological dimension and 0.83 for the sexual dimension, indicating good internal consistency reliability. All 211 patients also completed the DLQI, and Spearman correlation analysis showed a moderate negative correlation ($r = -0.50$, $P < .001$) between the original CECA10 (mean score, 23.82 ± 7.60) and DLQI (mean score, 10.11 ± 5.72), suggesting good criterion validity. The Chinese CECA10 score did not differ significantly between subgroups categorized on the basis of the numbers of

Table 4
Results of exploratory factor analysis.

Factor	Characteristic root	Variance contribution rate (%)	Accumulated variance contribution rate (%)
1	4.74	47.38	47.38
2	1.44	14.38	61.75
3	0.84	8.40	70.15
4	0.58	5.82	75.97
5	0.56	5.62	81.59
6	0.52	5.19	86.78
7	0.44	4.38	91.16
8	0.35	3.53	94.69
9	0.32	3.18	97.87
10	0.22	2.13	100.00

Table 5
Rotated factor component matrix.

Item	Factor 1	Factor 2
1	0.78	0.16
2	0.82	0.13
3	0.78	0.19
4	0.65	0.28
5	0.67	0.34
6	0.39	0.62
7	0.13	0.74
8	0.38	0.63
9	0.22	0.83
10	0.13	0.88

Absolute factor loading values are shown.

difficulty” or “with extreme difficulty” was 75.36% for the anxiety/depression dimension, 46.91% for the pain/discomfort dimension, 11.37% for the mobility dimension, 7.11% for the daily activities dimension, and 1.90% for the self-care dimension.

4. Discussion

The present study has developed a Chinese version of CECA10 with good test–retest reliability, internal consistency reliability, content validity, construct validity, and criterion-related validity. The brevity and understandability of the scale likely facilitated completion of the questionnaire by patients during treatment. The development of a Chinese CECA10 will facilitate the study of QOL in patients with CA, allowing comparison of Chinese data with those of international investigations. It is hoped that application of this new tool will further our understanding of how CA affects QOL in Chinese patients and facilitate future improvements in management strategies.

Throughout the development of the Chinese CECA10, significant attention was paid to cultural differences^[29,30] in expression between English and Chinese to ensure equivalence between the Chinese and original versions of CECA10. The back-translators were bilingual but had no medical background to minimize information bias. The scale items and instructions were modified according to issues that emerged during the panel review and pre-test. During the pre-test, the patients were asked to express each item in their own words to determine whether the item contents suitably reflected the original version.

Table 6
Mean CECA10 item scores in 211 patients with CA.

Item	Mean ± standard deviation
I am afraid that my disease would never disappear	2.23 ± 1.09
I am worried about whether or not my infection can be completely cured	2.11 ± 1.13
I am worried about disease deterioration or complications	2.40 ± 1.11
My mood is not stable at present (anxiety, depression, sorrow, uneasiness . . .)	2.55 ± 1.00
I basically feel no sense of security	2.75 ± 1.17
Being aware of this disease affects my daily life	2.34 ± 1.06
My libido is declined	2.87 ± 1.22
I feel worried when having sex	2.05 ± 1.06
I avoid sexual behavior	2.30 ± 1.17
My sexual quality and/or frequency is decreased	2.21 ± 1.08

The reliability of the Chinese CECA10 was evaluated as the test–retest reliability and internal consistency reliability.^[31] Test–retest reliability is an important measure of the dependability of a scale’s results,^[32] and a correlation coefficient > 0.7 is generally taken to indicate a stable scale. The ICC values for the Chinese CECA10 overall, its psychological dimension, and its sexual dimension were all 0.98, superior to those of the original scale.^[18] This may reflect the longer inter-test interval for the original version (15 days). Thus, the Chinese CECA10 has excellent test–retest reliability.

Internal consistency reliability^[31] reflects the homogeneity of individual scale items, with a value > 0.7 commonly accepted as good internal consistency. The Cronbach α values for the whole scale, psychological dimension, and sexual dimension were 0.88, 0.84, and 0.83, respectively, and Cronbach α decreased (to 0.50–0.79) with removal of any 1 item, showing that the Chinese CECA10 has good internal consistency.

Content validity assesses the extent to which a tool measures what it is supposed to measure, whether it contains adequate items, and whether the items are distributed appropriately.^[33] For the Chinese CECA10, I-CVI equaled 1 for every item, indicating that the contents of all items corresponded well to QOL impairment in patients with CA.

Construct validity^[34] evaluates the extent to which the scale corresponds with the test results and describes whether the scale structure is in line with its theoretical conception and construction. Factor analysis, commonly used to calculate construct validity, divides highly correlated observed variables into groups based on certain rules, with each group sharing a common factor that represents the basic structure of the scale. We identified 2 common factors that together explained 61.75% of the information. Items 1 to 5 were dominated by common factor 1 (psychological dimension), while items 6 to 10 were dominated by common factor 2 (sexual dimension). Except for item 6 (“being aware of this disease affects my daily life”), all items accounted for a relatively high factor loading in their dimensions. The discrepancy for item 6 may reflect the notion in Chinese patients that the influence of CA is mainly on sexual rather than other aspects of daily life. The relatively small sample size and cultural homogeneity may also have contributed. Although possible revision of item 6 could be considered in future research, the internal construction of the Chinese CECA10 overall was equivalent to the original version.

Subgroup analysis based on the numbers of warts, recurrences, and sites involved showed no significant differences between groups, indicating suboptimal discriminant validity; however, the *P* values only just exceeded .05. It is possible that our study was underpowered to detect discrimination due to the relatively low sample size. Furthermore, self-administration of the questionnaires may also have contributed to low discriminant validity. In future studies, data could be recorded by researchers to further explore the discriminant validity of this scale.

Criterion validity reflects the correlation between the instrument and its criteria. In practice, the relevance between a well-designed test and an important criterion is unlikely to be higher than 0.5, and it rarely exceeds 0.6 to 0.7. We chose the DLQI scale (for patients with dermatosis) as the criterion scale to assess CECA10, as it has been used previously for this purpose in international research^[18] and because it was the only specialized scale available in China for measuring QOL in patients with skin diseases. The DLQI score had a moderate negative correlation with the CECA10 score (*r* = -0.50), a slightly weaker correlation than that for the original version of CECA10 (*r* = -0.67),^[18]

indicating that the criterion validity of the Chinese CECA10 is ideal.

The demographic data showed that CA mainly affects young and middle-aged people who are at a sexually active phase. Most patients were male and more than half presented with CA recurrence. This is similar to the outcomes of epidemiological studies conducted in the Changzhi area, which showed that CA mostly affected people aged 20 to 40 years, with a male-to-female ratio of 1.33:1 and a slightly higher number of recurrent cases than new cases.^[35] Most of our patients were educated to a higher level than those of this previous study, likely reflecting regional differences (a higher education level in Beijing).

CA negatively influenced the QOL of patients with CA in both the psychological and sexual dimensions. The total CECA10 score in our patients was lower than that observed in an English study (44.1, $n=81$).^[11] All items scored low in the survey. Item 2 (“I’m worried about whether or not the infection can be completely cured”) ranked last in the psychological dimension, and item 8 (“I feel worried when having sex”) scored lowest in the sexual dimension, consistent with the results of previous research.^[11] Patients were particularly worried about prognosis and recurrence.

The average EQ-VAS score of our patients with CA was lower than that measured previously in 120,703 community residents aged 20 to 44 years (83.4–88.8 in males and 81.5–88.2 in females).^[28] The average EQ-VAS score of our patients with CA was similar to values determined in a Canadian study (65.1, $n=31$)^[10] and a previous Chinese study (65.2, $n=1358$).^[14] Our finding that QOL was lower in female patients than in male patients with CA is also consistent with other studies.^[11,14,15,20]

The EQ-5D survey revealed that anxiety and depression were common in our patients. Nearly half the patients suffered from moderate-to-severe pain or discomfort; other surveys have reported that, after treatment, patients with CA experience light-to-moderate pain during sexual activity.^[5,14,36] Anxiety and depression are common in patients with CA, who experience a sense of social isolation, shame, and embarrassment for having become infected with an STD.^[8,9,37] The characteristics and chronic nature of CA can aggravate anxiety and depression to reduce QOL.

A major advantage of CECA10 over EQ-5D-3L is that it contains a sexual dimension, allowing the impact of CA on sexual behavior and QOL to be determined. To the best of our knowledge, this is the first study in China to show that CA negatively affects the QOL of patients with CA in both the psychological and sexual dimensions. Our results highlight the need for the provision of psychological and emotional support to patients during treatment to improve QOL.

Our study has several limitations. First, this was a single-center study, so the findings may not be generalizable to other regions of China or other countries. Second, the sample size was relatively small, so the study may have been underpowered to detect differences between subgroups during the discriminant validity analysis. Third, sampling was not random, so it is possible that our results may have been influenced by systematic bias. Fourth, the questionnaires were self-administered; the recording of data by researchers in a future study will allow further exploration of discriminant validity. Fifth, a control group was not included, which would have permitted evaluation of the extent to which CA reduces the CECA10 score in patients with CA. Sixth, our study population contained only a small number of high-risk (homosexual or bisexual) individuals (27 of 211, 12.8%); data on the effects of CA on high-risk populations are limited,^[38] so further studies administering our survey to a much larger cohort

of homosexual/bisexual individuals are merited. Seventh, only 29 of the 211 study participants (13.7%) had had more than 1 sexual partner in the previous 6 months, so information about the influence of CA in people with a larger range of sexual partners remains scarce. Eighth, only 7 patients in our study (3.3%) were aged 18 to 19 years, and the mean age of the participants was 28.19 ± 7.16 years. Thus, the impact of CA on the QOL of younger people who have just become sexually active was not fully explored. It would be of great interest to extend this survey to a wider range of community members in a future study, so that QOL in patients with CA could be better assessed in people who are younger, are homosexual or bisexual, or have a larger range of sexual partners.

In addition, the overall clinical utility of the questionnaire could potentially be extended in the future by expanding the questionnaire to include options regarding knowledge and awareness of the HPV vaccine, as prophylactic vaccination against HPV has been reported to be effective against genital warts^[39] and cervical cancer.^[40] Furthermore, the addition of questions screening for symptoms of cervical cancer could potentially be of benefit in identifying individuals requiring additional clinical investigations, which in turn could facilitate early diagnosis and treatment.

5. Conclusion

The Chinese CECA10 has good test-retest reliability, internal consistency reliability, content validity, construct validity, and criterion-related validity for assessing QOL in patients with CA.

Acknowledgment

The authors thank and gratefully acknowledge Dr X. Badia and his research team for providing us with the English language version of CECA10 and guidance for our research study.

References

- Patel H, Wagner M, Singhal P, et al. Systematic review of the incidence and prevalence of genital warts. *BMC Infect Dis* 2013;13:39.
- Che YM, Ke WJ. Related factors of recurrent condyloma acuminata. *The Chinese Journal of Human Sexuality* 2010;19:19–21.
- Chang GJ, Welton ML. Human papillomavirus, condylomata acuminata, and anal neoplasia. *Clin Colon Rectal Surg* 2004;17:221–30.
- von Krogh G, Szpak E, Andersson M, et al. Self-treatment using 0.25%–0.50% podophyllotoxin-ethanol solutions against penile condylomata acuminata: a placebo-controlled comparative study *Genitourin Med* 1994;70:105–9.
- Maw RD, Reitano M, Roy M. An international survey of patients with genital warts: perceptions regarding treatment and impact on lifestyle. *Int J STD AIDS* 1998;9:571–8.
- Mortensen GL, Larsen HK. The quality of life of patients with genital warts: a qualitative study. *BMC Public Health* 2010;10:113.
- Dediol I, Buljan M, Vurnek-A Ivkovič M, et al. Psychological burden of anogenital warts. *J Eur Acad Dermatol Venereol* 2009;23:1035–8.
- Jeynes C, Chung MC, Challenor R. ‘Shame on you’: the psychosocial impact of genital warts. *Int J STD AIDS* 2009;20:557–60.
- Lawrence S, Walzman M, Sheppard S, et al. The psychological impact caused by genital warts: has the Department of Health’s choice of vaccination missed the opportunity to prevent such morbidity? *Int J STD AIDS* 2009;20:696–700.
- Marra C, Ogilvie G, Gastonguay L, et al. Patients with genital warts have a decreased quality of life. *Sex Transm Dis* 2009;36:258–60.
- Woodhall S, Ramsey T, Cai C, et al. Estimation of the impact of genital warts on health-related quality of life. *Sex Transm Infect* 2008;84:161–6.
- Zhang HJ, Wang Y, Han Y, et al. The influence of healthy education on the living quality of the condyloma patients. *Modern Nurs* 2004;10:180–1.

- [13] Zhu W, Li XH. A study on the life quality of patients with condyloma acuminatum and correlated factors. *Chinese J Behav Med Sci* 2008;17:609–10.
- [14] Shi JF, Kang DJ, Qi SZ, et al. Impact of genital warts on health related quality of life in men and women in mainland China: a multicenter hospital-based cross-sectional study. *BMC Public Health* 2012;12:153.
- [15] Qi SZ, Wang SM, Shi JF, et al. Human papillomavirus-related psychosocial impact of patients with genital warts in China: a hospital-based cross-sectional study. *BMC Public Health* 2014;14:739.
- [16] Wang SM, Shi JF, Kang DJ, et al. Impact of human papillomavirus-related lesions on quality of life: a multicenter hospital-based study of women in Mainland China. *Int J Gynecol Cancer* 2011;21:182–8.
- [17] Badia X, Colombo JA, Lara N, et al. Combination of qualitative and quantitative methods for developing a new Health Related Quality of Life measure for patients with anogenital warts. *Health Qual Life Outcomes* 2005;3:24.
- [18] Vilata JJ, Varela JA, Olmos L, et al. Validation and clinical use of the CECA, a disease-specific quality of life questionnaire for patients with anogenital condylomata acuminata. *Acta Derm Venereol* 2008;88:257–62.
- [19] Dominiak-Felden G, Cohet C, Atrux-Tallau S, et al. Impact of human papillomavirus-related genital diseases on quality of life and psychosocial wellbeing: results of an observational, health-related quality of life study in the UK. *BMC Public Health* 2013;13:1065.
- [20] Vriend HJ, Nieuwkerk PT, van der Sande MA. Impact of genital warts on emotional and sexual well-being differs by gender. *Int J STD AIDS* 2014;25:949–55.
- [21] Wang XL, Zhao TE, Zhang XQ. Assessment on the reliability and validity of the Dermatology Life Quality Index in Chinese version. *Zhonghua Liu Xing Bing Xue Za Zhi* 2004;25:791–3.
- [22] Chang TJ, Tarn YH, Hsieh CL, et al. Taiwanese version of the EQ-5D: validation in a representative sample of the Taiwanese population. *J Formos Med Assoc* 2007;106:1023–31.
- [23] Luo N, Chew LH, Fong KY, et al. Validity and reliability of the EQ-5D self-report questionnaire in Chinese-speaking patients with rheumatic diseases in Singapore. *Ann Acad Med Singapore* 2003;32:685–90.
- [24] Wang H, Kindig DA, Mullahy J. Variation in Chinese population health related quality of life: results from a EuroQol study in Beijing, China. *Qual Life Res* 2005;14:119–32.
- [25] Gao F, Ng GY, Cheung YB, et al. The Singaporean English and Chinese versions of the EQ-5D achieved measurement equivalence in cancer patients. *J Clin Epidemiol* 2009;62:206–13.
- [26] Luo N, Chew LH, Fong KY, et al. Do English and Chinese EQ-5D versions demonstrate measurement equivalence? An exploratory study. *Health Qual Life Outcomes* 2003;1:7.
- [27] Eriksson T, Torvinen S, Woodhall SC, et al. Impact of HPV16/18 vaccination on quality of life: a pilot study. *Eur J Contracept Reprod Health Care* 2013;18:364–71.
- [28] Sun S, Chen J, Johannesson M, et al. Population health status in China: EQ-5D results, by age, sex and socio-economic status, from the National Health Services Survey 2008. *Qual Life Res* 2011;20:309–20.
- [29] Blanchette MA, Normand MC. Cross-cultural adaptation of the patient-rated tennis elbow evaluation to Canadian French. *J Hand Ther* 2010;23:290–9. quiz 300.
- [30] Gjersing L, Coplehorn JR, Clausen T. Cross-cultural adaptation of research instruments: language, setting, time and statistical considerations. *BMC Med Res Methodol* 2010;10:13.
- [31] Kimberlin CL, Winterstein AG. Validity and reliability of measurement instruments used in research. *Am J Health Syst Pharm* 2008;65:2276–84.
- [32] Weir JP. Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. *J Strength Cond Res* 2005;19:231–40.
- [33] Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health* 2006;29:489–97.
- [34] Strauss ME, Smith GT. Construct validity: advances in theory and methodology. *Annu Rev Clin Psychol* 2009;5:1–25.
- [35] Hao XG, Feng XX. The Investigation and Analysis of 162 Cases in Condyloma Acuminate of Changzhi Area. *Guide of China Medicine* 2009;7:38–40.
- [36] Persson G, Dahlof LG, Krantz I. Physical and psychological effects of anogenital warts on female patients. *Sex Transm Dis* 1993;20:10–3.
- [37] Chandler MG. Genital warts: a study of patient anxiety and information needs. *Br J Nurs* 1996;5:174–9.
- [38] Lee Mortensen G, Larsen HK. Quality of life of homosexual males with genital warts: a qualitative study. *BMC Res Notes* 2010;3:280.
- [39] Navarro-Illana E, López-Lacort M, Navarro-Illana P, et al. Effectiveness of HPV vaccines against genital warts in women from Valencia, Spain. *Vaccine* 2017;35:3342–6.
- [40] Lu B, Kumar A, Castellsagué X, et al. Efficacy and safety of prophylactic vaccines against cervical HPV infection and diseases among women: a systematic review & meta-analysis. *BMC Infect Dis* 2011;11:13.