Validization of the czech version of specific questionnaire for genital warts
(Cuestionario Específico en Condilomas Acuminados – CECA10)
in selected population of czech women

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ABSTRACT

Background: Condyloma acuminata is the most common sexually transmitted disease that has a negative impact on the quality of life. Cuestionario Especifico en Condilomas Acuminados is a specific questionnaire that allows you to measure the quality of life for this disease. The questionnaire is divided into 2 dimensions - the sexual and the emotional.

Aim: The aim of the study was to create a verified and reliable Czech version of the Cuestionario Especifico en Condilomas Acuminados.

Methods: The Czech version of the questionnaire was verified by a study on a sample of 60 women. The reliability was assessed using Cronbach's alpha marker. The validity was assessed using Pearson's correlation coefficient and confirmation factor analysis and cluster analysis.

Results: The internal consistency of the questionnaire confirms the value of Cronbach’s alpha 0.97. Criterion validation has been confirmed. The correlation between the sexual dimension and the sexual satisfaction aspects of the questionnaire are high - both instruments measure the same components. The same is true for the correlation between the emotional dimension and the overall mental health part of the Short Form 36 questionnaire (Life Quality Test, shortened version 36). The confirmatory factor and cluster analysis confirmed that the structure of the questionnaire exactly corresponds to the two dimensions considered.

Conclusions: The Czech version of the questionnaire Cuestionario Especifico en Condilomas Acuminados was created. It can be tailored to be used to assess the quality of life of women with condyloma acuminata. This is a short questionnaire that has 10 items and evaluates the quality of life in these two dimensions.

KEY WORDS
condyloma acuminata, quality of life, validity, reliability, measuring instrument

INTRODUCTION

Condyloma acuminata (CA) or genital warts is a benign epithelium neoplasm caused by (in 90% of cases) an infection of the human papillomavirus (HPV) type 6 and 11. CA belongs to the most common sexually transmitted diseases (STD) with a yearly incidence of 496 cases per 100,000 inhabitants (1). In spite of the fact that there are a number of therapies, they have a high rate of recurrence form 40 to 60%. (2). Due to its chronic characteristics, CA creates a great psychological pressure for patients, which causes changes in the quality of their sexual lives and the decrease in the of Quality of Life - QOL (3,4).

Current health care should be aimed, not only at the given disease, but should also monitor the impact of this disease on a patient's life and the changes in it. A part of this complex healthcare is also the evaluation of the quality of life related to the health (Health Related Quality of Life – HRQL).

For the purpose of the evaluation of the quality of life, several methods could be used: generic (both for healthy and sick people), specific (for patients with one specific type of a disease or a set of symptoms),
or eventually a mixed method. For some specific diseases, usually several world-wide questionnaires are at the individual’s disposal for evaluating HRQL, which, though, may differ in their basic characteristics. For genital warts, such a selection does not exist. We can use the HIP questionnaire (HPV Impact Profile), which is aimed at HPV infected patients, not at patients with cancer. Another questionnaire, which is available, is the questionnaire CECA10 (Cuestionario Específico en Condilomas Acuminados), which is a specific questionnaire that measures the quality of life in men and women with genital warts.

Generic tools used for measuring the quality of life related to health in some foreign studies showed that the patients with CA have a decreased QOL (5-15). However, these tools are not optimized for the evaluation of sexual, psychological and emotional areas of QOL in patients with CA. That is why the team of Spanish authors developed a specific questionnaire, CECA10, which was designed especially for patients suffering from this disease (16). At present, the questionnaire is available in Spanish, English and Chinese (Mandarin) (2, 9, 16). It was proved that CECA10 has good reliability and validity, when applied in European and Chinese patients with genital warts (2, 9). The studies, which used CECA10, found that the patients with CA have a decreased quality of life; they show worries and anxiety from the disease and have sexual problems. (7-9, 14).

Unfortunately, in the Czech Republic, no study has been carried out, which would assess HRQL in patients with genital warts, neither with the use of one of the generic questionnaires measuring the quality of life related to health nor with any specific questionnaire. The aim of this study was to translate the English version of CECA10 into Czech and to assess the reliability and the validity of the Czech version of the CECA10 for evaluating QOL in a selected population of Czech women with genital warts.

THE AIM OF THE WORK
This study has two determined goals:
1. To create a Czech version of the CECA10,
2. To verify the reliability and the validity of the Czech version in a selected population of Czech women.

METHODOLOGY
The sample of respondents included 60 women having a genital wart diagnosis. The respondents were intentionally selected. The criteria for the selection were as follows: 1st. Presence of genital warts, 2nd. Age (18 years and higher), 3rd. They have to be clients of the selected gynecological consulting rooms, 4th. Regarding the use of the questionnaire GRISS (The Golombok-Rust Inventory of Sexual Satisfaction), the next criterion for including the woman in the research sample was having at present a heterosexual relationship (this criterion was not known in advance), and 5th. The last criterion was the absence of another disease (again not known in advance).

The criteria for exclusion were: 1st. Homosexual orientation, 2nd. Present homosexual or bisexual relation, 3rd. The presence of any other disease other than CA, 4th. Refusal to participate in the research.

All respondents provided written consent for their participation in the research. In the Ústí nad Labem region, several gynecological outpatient departments were addressed with the request for cooperation in the research. Most, if not all of them, displayed interest in it. The addressed departments were selected in relation to the accessibility for the authors of this study and as well as according to the previous positive experience with their cooperation in other research tasks.

To ensure a larger sample of respondents, in the course of this research, another outpatient department in Prague, specializing in the cure of genital warts, was also addressed. This department showed interest in this cooperation. The respondents were thus addressed in 4 selected gynecological outpatient departments in the Ústí region and 1 gynecological outpatient department in Prague, during the November 2016 and November 2017 period. From the point of view of age distribution, the sample consisted of women aged 18 to 45 with an average age of 33.1 years.

A necessary condition for carrying out a broader study, whose part was also creating a Czech version of questionnaire CECA10, was the informed consent of the client with the participation in the research. The respondents were also sent an induction letter, in which they were given basic information about the research and its aim.

Before the beginning of the research, the approval of the Ethical committee of Krajská zdravotní a.s. – Masaryk hospital o.z. in Ústí nad Labem was acquired. This approval was awarded by the Ethical committee on the 23rd of November, 2016. The consent of the medical institutions, in which data collection were carried out, was also acquired.

Data were elaborated by means of the program, Microsoft Excel 2007. For statistical purposes, the programme SW STATISTICA, v. 11 was used.

A battery of questionnaires was created, which consists of several questionnaires. These questionnaires investigate the quality of life (Test of the quality of life – Short Form-36, SF-36), sexual satisfaction (GRISS)
and the quality of emotional and sexual life in women with genital warts (CECA10). A questionnaire battery was completed by sociodemographic questions (age, education, employment, number of sexual partners in the last 6 months, sexual orientation) and clinical questions (extent and localization of warts, length of the disease, relapse, and previous treatment).

Specific questionnaire condyloma acumínata – Cuestionario Específico en Condilomas Acumina-dos, in Spanish (CECA10)

This specific questionnaire was created by the team of Spanish authors in 2005. The original version of the questionnaire contained 22 items and the questionnaire was marked by the abbreviation CECA 22. On the basis of Rasch analysis, the team of authors created a shorter version of the questionnaire with only ten items (CECA10), which is used in other foreign studies. At present, there is a Spanish, Chinese and English version, and the English version was also created by the Spanish authors for the purposes of publication in foreign professional articles.

The aim of CECA10 is to investigate and assess the quality of sexual and emotional life. Because of the specificity of the items, it is designed only for respondents with anogenital warts. It could be administrated both to men and women. The questionnaire is divided into 2 dimensions – the sexual and the emotional dimension. The first six items in it correspond to the emotional dimension (marked by the authors as CECA6) and the last four belong to the sexual dimension (factor CECA4).

The entire questionnaire is related to the previous seven days of the respondent’s life before having completed the questionnaire. Each question has a selection of 5 possible replies. The responses are ordered according to the Likert scale (always, nearly always, sometimes, hardly ever, never). The only exceptions are questions number 3 and 5, where there is one more possible response, “non-applicable”. In the emotional dimension, it is possible to achieve a total of 6 – 30 and in the sexual dimension it is 4 – 20. The whole range of points is 10 – 50. It generally means that the higher score that is achieved by the respondent, the better her quality of life is. (16).

The values of Cronbach alpha in the Spanish version of the questionnaire are 0.86 and 0.91 (for factors CECA6 and CECA4). The coefficients of the reliability of the test-retest are 0.76 and 0.82 (9). The English version CECA10 proved its validity, reliability and equality with the Spanish version. The English version CECA10 has already been used in many countries, including Great Britain, the Netherlands and Finland (7, 8, 14, and 20). The English version CECA22 has been used in Great Britain and Croatia. (5, 13). The values of Cronbach alpha in the Chinese version are 0.88, 0.84 and 0.83 for the entire score for the emotional and sexual dimensions. The coefficient of the reliability of the test-retest is 0.98. The criterial validity was also investigated in the Chinese version (r = -0.50) and the factor analysis was carried out (the items are grouped into two domains). Also the Chinese version CECA10 showed good reliability and validity (2).

RESULTS

Linguistic validation of the questionnaire CECA10

The Czech version of CECA10 was translated from the English version of the tool. The translation was carried out independently by three specialized translators and subsequently a check of the individual items (especially for the correctness of their translations) was performed. By comparing the individual items in three versions, one resulting Czech version of the questionnaire CECA10 came into existence. From each translation, the best quality parts were selected and necessary corrections were implemented. This is how the first Czech translation came into being. Then the reverse translation was accomplished, by two other translators, who translated the Czech version into English without knowing the original one. Both had English as their mother tongue, so they are native speakers. The English reverse translations were, concerning their content and significance, a precise translation of the first Czech translation. We compared the reverse translations into English to the text of the original English questionnaire. We concentrated on the content and significance diversions between the original version and these reverse translations. Because the sentences are short and simple, in this case, they were equivalent both in the content and form.

After that, we graphically modified the Czech version of questionnaire CECA10 and then distributed them to the respondent sample (n = 10). The women should have completed the questionnaire and eventually present their remarks concerning both the content and the form of the questionnaire. There were no remarks or requirements to the questionnaire, so that is why we did not implement any further changes to the Czech version of CECA10.

Before the beginning of the research, the main author of questionnaire CECA10 was addressed and asked for their consent for the creation of the Czech version of CECA10, its publication in the professional scientific journals and so on. This consent from the main author of the questionnaire was acquired.
Reliability of the Czech version of CECA10

The reliability, as an internal consistence of items, was investigated by means of the Cronbach alpha test. This measures the dependence among individual items and thus it is a ratio of the internal consistency of the test. The values of Cronbach alpha are 0.98 and 0.96 for factors CECA6 and CECA4 (Table 1).

It was proved that there is not an excessively tight dependence between the evaluation of emotional and sexual life (Graph 1). The corresponding index of determination is 0.102, i.e. the linear regression model (see the red straight line in Graph 1) explains the variability of data only from about 10%. The regression model is statistically significant (p = 0.013), in detail it is like this:

\[ CECA6 = 12.321 + 0.540 \times CECA4 \]

Table 1 Reliability of CECA10

|   | MEANS | SD  | CA  | AIIC |
|---|-------|-----|-----|------|
| CECA6 | 18.20 | 7.40 | 0.98 | 0.89 |
| CECA4 | 10.89 | 4.37 | 0.96 | 0.86 |

Notes: SD (standard deviation), CA (Cronbach’s alpha), AIIC (average inter-item correlation)

Graph 1 Reliability of CECA10 – the relationship between CECA4 and CECA6

With the growing figure for the evaluation of CECA4, the evaluation of CECA6 is also on average proportionately growing (in which case we can claim, that the increase in the evaluation of CECA4 by 2 points means the increase in CECA6 by roughly 1 point). In this sense, the reliability as an internal consistency of both components CECA10 has been confirmed.

Validity of the Czech version CECA10

We assessed the criterial (i.e. parallel) validity by means of the Pearson correlation coefficient. Then we also assessed the validity by means of confirmation factor analysis and by means of cluster analysis.

To find out, whether the questionnaire really measures what it should measure, it was necessary to compare the data, required by the use of one tool, with the data, acquired by a different tool, which should investigate the same area of measurement. So the parallel validity was investigated by means of the correlation coefficient between these two measuring tools. Since the questionnaire CECA10 consists of two dimensions (emotional and sexual), two measuring tools or their parts have been used for comparison. The data evaluating sexual dimension were compared to the data acquired by questionnaire GRISS (CECA4 versus total score in GRISS). The data evaluating emotional dimension were compared to the data acquired by questionnaire SF-36, namely to its part – the index of overall mental health (MCS), which is calculated as an average of all dimensions belonging to the psychological component (CECA6 vs. MCS).

A good match was found between the evaluations by the total score of GRISS and CECA4 (Graph 2). The match is in the sense of indirect proportion – the growing values of one indicator correspond to the decreasing values of the second indicator. The related correlation coefficient is therefore negative (r = 0.930). It is an extraordinary high rate of correlation, the rate of match is about 90% (r² = 0.903).
A good match was also found between the evaluations by means of MCS and by means of CECA6 (Graph 3). The match is in the sense of direct proportion – the growing values of one indicator correspond to the growing values of the second indicator. The related correlation coefficient is therefore positive \( r = 0.950 \). And again, it is an extraordinary high rate of correlation, the rate of match is about 90\% \( r^2 = 0.903 \).

For testing the validity, the factor analysis for all 10 items was carried out. A model with two factors was created. The results are shown in Table 2.

| položky  | Factor 1       | Factor 2       |
|---------|----------------|----------------|
| CECA1   | −0,897496      | 0,339118       |
| CECA2   | −0,906355      | 0,267533       |
| CECA3   | −0,911788      | 0,235905       |
| CECA4   | −0,893961      | 0,343725       |
| CECA5   | −0,876746      | 0,370510       |
| CECA6   | −0,895738      | 0,366251       |
| CECA7   | −0,494506      | −0,821126      |
| CECA8   | −0,634070      | −0,682948      |
| CECA9   | −0,622924      | −0,707721      |
| CECA10  | −0,585700      | −0,754948      |
| Prp.Totl| 0,620619       | 0,284327       |

Notes: Prp.Totl. (total – the percentage significance of a given factor to explain complete data)

As variables, contributing to Factor 1, items CECA1 to CECA6 were detected (see grey backgrounded values in Table 2 in column Factor 1). As variables, contributing to Factor 2, items CECA7 to CECA10 were detected (see values in Table 2 in column Factor 2, where only CECA8 is not grey backgrounded, but the corresponding value goes close to the limit of 0.7, for “sufficiently convincing”).

The structure of the questionnaire thus precisely corresponds to two considered domains. The rate of ranking individual items among individual domains (ten variables), and at the same time the rate of their mutual similarity are illustrated in Graph 4, which shows the so called “main components”. The correlation of individual items is illustrated in Table 3. All
items are mutually positively correlated (i.e. higher values of the given item mean higher value in another item).

The division into two domains is also obvious from this structure – significantly high values of the correlation coefficient (more than 0.8 – in Table 3 with grey background) are both among items CECA1 to 6 and among items CECA7– 10. The least correlated item with the others is item no. 7 (which was demonstrated in Graph 4, as its transfers further from the others). The same behaviour is also demonstrated in item no. 10.

Table 3 The correlation items of CECA10

|     | CECA2 | CECA3 | CECA4 | CECA5 | CECA6 | CECA7 | CECA8 | CECA9 | CECA10 |
|-----|-------|-------|-------|-------|-------|-------|-------|-------|--------|
| CECA1| 0.886 | 0.898 | 0.903 | 0.880 | 0.921 | 0.181 | 0.324 | 0.299 | 0.286  |
| CECA2| –     | 0.855 | 0.869 | 0.880 | 0.904 | 0.228 | 0.419 | 0.356 | 0.316  |
| CECA3| –     | –     | 0.897 | 0.860 | 0.862 | 0.272 | 0.388 | 0.405 | 0.352  |
| CECA4| –     | –     | 0.889 | 0.914 | 0.161 | 0.326 | 0.311 | 0.274 |        |
| CECA5| –     | –     | 0.918 | 0.121 | 0.297 | 0.308 | 0.305 | 0.233 |        |
| CECA6| –     | –     | 0.136 | 0.331 | 0.331 | 0.305 | 0.242 |        |        |
| CECA7| –     | –     | –     | 0.839 | 0.854 | 0.890 |        |        |        |
| CECA8| –     | –     | –     | 0.833 | 0.844 |        |        |        |        |
| CECA9| –     | –     | –     | –     | 0.873 |        |        |        |        |

Note: Empty fields are not missing, this table is symmetric and it is unnecessary to provide the same data.

Graph 4 Factor1 and Factor2

It was also possible to elaborate the data by means of cluster analysis. The requirement to divide 10 variables into two clusters finished with an analogical result, cluster 1 = variables CECA1 – 6, cluster 2 = variables CECA7 – 10. In this method, the standard result is a graph showing a gradual clustering of the most similar variables in the tree structure – tree clustering (Graph 5). In this graph, the division into two groups (domains) is obvious. In the “upper” group, the so called initial core is created by items 5 and 6, and the last item (the furthest from the core of this cluster) is item 3, on the contrary, in the “lower” part, the core is created by items 7 and 10 and on the contrary, the furthest from the core is item 8. Graph 5 is thus in accordance with Graph 4 from the factor analysis”; according to both of them, e.g. item 8 is within the framework of its domain, the closest to the second domain. At the same time, this graph is in accordance with Table 3 for correlation coefficients. Items 7 and 10 came out as the least correlated with the others, so that is why they were selected by the mathematical algorithm as the core of the second cluster.
DISCUSSION
This study developed the Czech version of questionnaire CECA10 with a good reliability and validity. The development of the Czech version will facilitate the evaluation of the quality of life in patients with genital warts, which will enable an objective comparison of Czech data to the results of foreign studies. CECA10 is a tool of 10 items, where the items, in consistence with the original version, are grouped in two domains – emotional and sexual.

Reliability
The excellent internal consistence of the Czech version of questionnaire CECA10 is supported by the level of Cronbach alpha, which is 0.97 for CECA10, 0.98 for CECA6 and 0.96 for CECA4. The authors of questionnaire CECA10 present the following values of Cronbach alpha for the original version: 0.86 for CECA10, 0.84 for CECA6 and 0.86 for CECA4 (16).

The reliability of the Spanish version was also examined by other authors a few years later. In their study, they present a very good internal consistency with values of Cronbach alpha 0.91 for the total score, 0.86 for emotional dimension and 0.91 for sexual dimension. The authors did not state, for which time period the test-rest was carried out (9). The results of testing the reliability of the Chinese version of CECA10 are also available. In this study, a good internal consistence of the questionnaire was confirmed; the values of Cronbach alpha were 0.88 for CECA10, and 0.84 and 0.83 for emotional and sexual dimension. The correlation coefficient for test-retest reliability was 0.98. In the Chinese study, the repetition of the test was carried out after 15 days (2). We also had to decide, when planning the research, if we should verify the reliability of the questionnaire by means of test-retest. In this case, at least a 3-month interval is recommended between the questionnaires, so that the so called “training” did not come into effect, but at the same time there is a risk that during such a long time significant psychological changes may appear. And because the authors of the questionnaire recommend that it should concern the last 7 days before completing it, we decided not to use the test-retest method with regard to the above mentioned disadvantages. So it may be questionable, which corresponding value the correlation coefficients of the test-rest in other foreign studies have.

Validity
The factor analysis showed an absolutely clear structure of the questionnaire CECA10. As well as in the Chinese version of the questionnaire, two factors were identified, which correspond to two dimensions. In our case, Factor 1 included items 1 – 6 (emotional dimension) and Factor 2 included items 7 – 10 (sexual dimension). In the Chinese version of the questionnaire, the results were very similar. Factor 1 included items 1 – 5 and Factor 2 items 6 – 10. The authors concentrated especially on item number 6, which, according to their analysis, belonged to sexual dimension. They believe that item 6 could reflect the opinion of Chinese patients, that CA influences their sexual life first of all. In spite of that, they offer the possibility to revise item 6 in future research. They claim that the internal structure of the Chinese version of CECA10 is equivalent to the original version of the questionnaire (2). In our case, we concentrated on item 8, which was by factor and cluster analysis correctly ranked among sexual dimension items, but unlike the other items from this group, it was the closest to the second group (emotional dimension). If we have a closer look at item 8, we dare to claim that the results of both analyses are logical. The statement in item 8 is
the only one within the sexual dimension, which relates to emotion, namely, to the fear of having sexual intercourse. Therefore, we believe that the revision of item 8 for further research is not necessary.

In the Czech version of CECA10, we assessed criterial (parallel) validity by means of the Pearson correlation coefficient. Emotional dimension was correlated by SF-36 tool, especially by its part of the index for total psychological health. The correlation coefficient reached the level of 0.95, which means a high level of correlation.

A very similar result was achieved by the correlation of the sexual dimension to the total score of questionnaire GRISS. The correlation coefficient resulted in a negative value, because the match here is in the sense of indirect proportion – the growing values of one indicator correspond to the decreasing values of the second indicator. The value for the coefficient is -0.93. Correlation of individual scores for dimensions CECA10 with two different measuring tools was carried out probably exclusively in our research. In other research studies, correlation of the total score for CECA10 with other measuring tools was used. Guo et al. 2018, chose as the measuring tool the DLQI (Dermatology Life Quality Index) for the correlation of the Chinese version. This tool is designed for patients with dermatologic problems. They chose it due to the fact that it is the only specialized tool for patients with dermatologic diseases available in China. The correlation coefficient between the Chinese version of CECA10 and DLQI reached the level of -0.50 (2). Also Vilata et al. 2008, correlated the total score of the Spanish version of CECA10 with questionnaire DLQI. The correlation coefficient was -0.67 in this case (9). In comparison to these two studies, the criterial validity in our case reached a surprisingly high level. According to Guo et al. 2018, it is very rare, if the correlation coefficient is within the interval 0.60 – 0.70 (2). In our study, we reached much higher values. The reason may be a relatively small sample of respondents (60), unlike the Chinese version (211 respondents) and the Spanish study (247 respondents). Another difference is that in our study only women were included, whereas in other studies also men participated. These two foreign studies, and also some other foreign studies, correlated the quality of life of women and men with CA. The results show that in comparison to men, the women have a significantly lower total QOL. Worse results were also achieved by women in emotional and sexual dimensions (2, 7, 9, 11, 12). That is why the homogeneity of the composition of respondents (women only) could explain the high rate of correlation.

Questionnaire CECA10 was used also in some other foreign studies. Unfortunately the authors did not verify its reliability and validity. However, they always used at least one other measuring tool for measuring the QOL and according to their results, it is obvious that if the respondents achieved a low score in questionnaire CECA10, the lower quality of life was found also by the other tool (7, 8, 14).

LIMITATIONS

This study has several limitations. 1 – Our examined sample of the population is created only of women. 2 – The research was carried out in selected gynecological outpatient's departments in the Ústí region and in one outpatient department in Prague. 3 – The size of the examined sample is relatively small. The results thus cannot be generalized for the whole Czech population. In spite of that, we can claim that the questionnaire is validated for the selected population of the Czech women. It is therefore in place to execute another study, which would include a larger sample of respondents and this sample should include both women and men. 4 – The questionnaires were filled in by women themselves. If they were filled in, in cooperation with the respondent, by research workers, they could concentrate on the examination of other areas, such as discrimination validity.

CONCLUSION

We have created a Czech version of the specific questionnaire CECA10 for the evaluation of the quality of life in patients with genital warts and we succeeded in verifying its reliability and validity in the selected population of Czech women.

In the Czech clinical practice, there has not been any study like this up to now, a study which would evaluate and assess the level of the quality of life in patients with genital warts and would deal with a special measuring tool, which could be applied in patients with genital warts. The quality of life of these patients also could be measured by generic measuring tools, but we decided to create a Czech version of questionnaire CECA10, which would be exclusively aimed at patients with genital warts. The Czech version of CECA10 will thus serve for future research and will enable an international comparison to other studies.

As we have already mentioned above, it would be good to validate the Czech version of CECA10 on a more representative sample of respondents. And for acquiring objective results, men should also be included.

We can say that questionnaire CECA10 is a suitable tool for evaluating the quality of life of women
with genital warts. It is well understandable, easy and fast to fill in. The results are easily evaluated and interpreted. The Czech version of CECA10 is at the disposal of the author of this article.

This validation study came into being within the framework of larger research, aimed at the evaluation of the quality of life of women with genital warts and its correlation to a healthy group. The results of this research are currently being prepared for publishing.

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