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VALIDATION OF THE GERMAN VERSION OF THE "ICIQ VAGINAL SYMPTOMS QUESTIONNAIRE" (THE ICIQ-VS GERMAN): THE GERMAN TRANSLATION OF THE ICIQ-VS- AN OBSERVATIONAL STUDY

Hypothesis / aims of study
Several clinic internal questionnaires exist for the evaluation of vaginal symptoms, but there is still a deficit of evaluated questionnaires. In 2006 the International Continence Society developed a validated vaginal questionnaire contenting the sexual aspect as well as pain, pressure and quality of life items (1). The ICIQ-VS has not been translated yet into German. We here report about the translation and validation process of the ICIQ-VS (German).

Study design, materials and methods
For establishing a cultural adaptive equivalent in German the recommendations from Guillemin et al. (2) was followed extensively. Two Germans translated the original ICIQ-VS independently into German. Both translations were harmonized and afterwards back-translated by two independent native English speakers. The harmonized back translation was then compared to the original version respective grammar and semantic. The translation was considered to be equivalent to the original questionnaire. The German version was submitted to three further bilingual persons and final suggestions were taken into account. The final version was pre-tested in a pilot study on ten patients. The patients of the pre-test study understood the questionnaire without further explanation. No comprehension difficulties were found. The final version of the ICIQ-VS was given to 58 patients suffering from genital prolapse higher than grade one POPQ (pelvic organ prolapse quantification) and 51 patients without vaginal affection. Patients suffering from genital descensus were seen in the gynaecological department of our clinic between May and July 2007 and underwent subsequently laparoscopic sacropexy. This group had to fill up the questionnaire eight days before surgery, one day before surgery and one year after surgery. During the first and second submission of the ICIQ-VS no clinical or surgical intervention was performed. Patients suffering from genital descensus without a surgical intervention were excluded. Patients of the control group suffered from internal diseases (hypertension, gastric problems) and were hospitalized at the internal department (n= 12) or were suffering from breast, uterine or ovarian symptoms (adnexitis, uterus myoma, hypermenorrhoe or breast cancer, n= 39). Symptoms of a vaginal prolapse were exclusion criteria for the control group. The control-group filled up the questionnaire on any day, seven days later and one year later. The ICIQ-VS (German) contents of 14 questions and covers the division's pain, pressure, sexual matters and life quality. Thirteen questions are subdivided into two parts (a and b). For evaluation a ranking system exists. A maximum of 53 points is available for questions one to eight (vaginal questions, part a) and 58 points for questions ten to 13 (sexual questions, part a). The quality of life score (part b) is reflected in the b part of each question and ranges from zero to ten. Question 14 reflects the general influence of impairment and also ranges from zero to ten. The psychometric properties of the questionnaire were assessed using SPSS and Starter TM.

Results
In our pre-test analysis all items were well interpreted and filled in by all ten patients. In the main study mean age was 64 years (range35 to 87 years) in the vaginal group and 56 years (range 25-86 years) in the control group. No changes from the original format were observed after translation and cultural adaptation. There was no hint of a systematic comprehension difficulty concerning any question in both groups. We had a constant interval of seven days between ICIQ-VS first interview and retest in both groups.

Internal consistency was high (standardized Cronbach alpha coefficient range 0.71-0.78). The test retest reliability (stability over time) was measured by weighted Kappa index and was stable for both groups (0.71-0.88). Sensitivity to change was excellent (Wilcoxon sign rank test, $p<0.01$-$p<0.001$). The impact of vaginal symptoms of quality of life was worse in the vaginal than in the control group (tab.1). Construct validity revealed statistical significant differences between groups (tab.2). Response rate was 96 % in the vaginal group and 98 % in the control group. We had low rates of missing data (vaginal group 3.6 %, control group 3.6 %). Thus the content validity was excellent. We cannot state concurrent validity as no comparable questionnaire concerning vaginal symptoms was available in German.

Interpretation of results
Our study confirms the psychometric properties of the ICIQ-VS German respective validity (construct and content), reliability, sensitivity and consistency. Consequently, users can be confident that it reliably measures what is intended and provides a legitimate and valid summary of the level of vaginal symptoms and their impact on quality of life. Moreover, it is sensitive to change and can reliably quantify changes in symptom levels following treatment.
Compared to clinic internal questionnaires which are not evaluated it covers all important domains. Questions are not related to each other but contain different aspects of vaginal symptoms. ICIQ-VS (German) provide an instrument for characterising the severity of vaginal symptoms, measuring their impact on quality of life and evaluating treatment outcome.

Concluding message: The ICIQ-VS has been translated and evaluated successfully into German. To our knowledge this is the first evaluated vaginal questionnaire which is available in German. During the last years the broad use of the English version has proven its relevance for clinical research. We expect the same to this German version.

	Vaginal group T1	Vaginal group T2	Vaginal group T3	Controls T1
Vaginal symptoms score (maximum=53)				
Mean score (SD)	18.91 (9.5)	19.63 (9.86)	7.13 (8.42)	5.8 (7.05)
Median score (range)	17.5 (2 - 41)	18.5 (2-41)	4 (0-30)	2 (0-30)

Sexual matter score (maximum=58)				
Mean score (SD)	14.83 (14.06)	17.58 (16.89)	5.58 (8.75)	2,82 (8.16)
Median score (range)	11 (0-50)	11 (0-58)	0 (0-30)	0 (0-38

Table 1: Verification of the scoring system: Statistical results comparing the mean vaginal and sexual symptoms score for vaginal group at time one, two and three (T1-T3) and control group at time one

	Prevalence vaginal group (n=56)	***Bothersome ness median***	***Prevalence vaginal group (n=56)***	***P value (construct validity)***
Vaginal symptoms				
Dragging pain	69.9 %	2.0 (0-4)	50 %	<0.01
soreness	46.4 %	0.0 (0-3)	28 %	<0.05
Reduced sensation	53.3 %	1.5 (0-3)	22 %	<0.01
Loose vagina	66.1 %	2.0 (0-4.5)	22 %	<0.001
Lump inside	76.8 %	5.5 (2-9.5)	8 %	<0.001
Lump outside	67.9 %	7.0 (0-9,5)	8 %	<0.001
Dry vagina	64.3 %	3.0 (0-5.5)	42 %	<0.01
Faecal evacuation	8.9 %	0	2 %	<0.01
Sexual symptoms				
Tight vagina	17.9 %	0	10 %	0.217
Sex life	21.4 %	-	56%	<0.01
Worries	66.6 %	2.5 (0-4.5)	13.3 %	<0.001
Relationship aff	25 %	0 (0-1)	6.7 %	0.19
sex life spoilt	-	3.0 (0-8)	-	<0.001
Quality of life	-	7.0 (3-8.5)	-	<0.001

Table 2 Percentage of woman reporting symptoms in the vaginal and control group

References

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Specify source of funding or grant	**No funding, no grant**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**We made an observational study. All patients were informed about the questionnaire and the purpose of this study. All patients agreed to fill in the questionnaires three times. Patients could refuse participation at any time.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**