

## VALIDATION OF THE PORTUGUESE VERSION OF THE GAUDENZ-FRAGEBOGEN: USED FOR DIAGNOSIS OF URINARY INCONTINENCE

### Hypothesis / aims of study

The Gaudenz-Fragebogen, used for the differential diagnosis of urinary incontinence gained popularity among the German-speaking countries since its first publication, and has been widely utilized as a screening test[1]. Being used with the goal of establishing an initial and differential diagnosis of female UI, its application yields the type of UI by means of its scores[2]. Translated and adapted to the Brazilian culture, it demonstrated to be easily understandable when applied to female populations[3]. However, the mere cultural adaptation does not guarantee that the translated and adapted instrument can be considered as consistent and reliable. A second phase is necessary with the objective of verifying the instrument's measurement properties - reliability and validity.

Thus, the aim of the present study is to validate, for the Brazilian culture, the final version of the Gaudenz-Fragebogen.

### Study design, materials and methods

The presented work encompasses a methodological study and addresses the investigation of obtaining methods, data organization and analysis, which aims at the elaboration, adaptation, validation and evaluation of instruments and research techniques.

The Gaudenz-Fragebogen is a specific and self-administered instrument, developed originally in the German language, made of 16 dichotomous items which allow for two final scores: the urge-score, which grades urge urinary incontinence (UUI) and the stress-score, which grades for stress urinary incontinence (SUI). Each item's grade varies between 0 and 3 and the sum of the final scores falls between 0 and 26 both for urge-score and stress-score. For an urge-score between 13 and 26, and for a stress-score between 0 and 6 the probability of an UUI result is 97%. For a stress-score between 13 and 26 and an urge-score between 0 and 6 is the probability of an SUI result is 87%[2].

The Gaudenz-Fragebogen, after being translated and adapted to the Brazilian culture[3], was submitted to a psychometric properties evaluation process.

The final version of the questionnaire was verified to assert its reliability, by way of testing-retesting - which verifies the precision and coherence capacity of an instrument to produce the same results when used more than once - and submitted to the concurrent validity criterion, whose golden standard, defined for the research was the urodynamic study of patients with UI complaints.

The Gaudenz-Fragebogen and a specific questionnaire for data collection of sample characterization were applied in a group of women presenting complaints of urinary incontinence. In order to verify reliability a test-retest was applied to 60 of these women. For the concurrent criterion validity assessment, 168 diagnostic reports - attributed by the urodynamic study - were considered, having been distributed in the following groups: 78 cases of SUI (46.4%), 38 cases of UUI (22.6%), 34 cases of mixed urinary incontinence (MUI) (20.3%) and 18 cases with "normal" urodynamic study results (10.7%).

### Results

The women were between 21 and 87 years old, with low levels of education and financial resources, being 103 of them in the post-menopause period. Most of these (88.7%), during their reproductive phase, experienced vaginal birth, and 89% presented co-morbidities.

The adapted instrument showed high reliability by test-retest proved stability, expressed by the Intraclass Correlation Coefficient (CCI=0.99).

In reference to the concurrent criterion of validity assessment, the Gaudenz-Fragebogen - according to the cutting point of its two scores - wasn't able to discriminate adequately the UI type, and presented low sensibility to the SUI (9%) and UUI (44.7%). In relation to the specificity, the results were 96.7% for SUI and of 70.0% for UUI.

### Interpretation of results

Analyzing studies that used the Gaudenz-Fragebogen it was verified that the instrument is in fact popular in German-speaking countries. However, in the critical analysis of six of these studies, in which the Gaudenz-Fragebogen was utilized, it was observed that the instrument was not submitted to the measurement properties evaluation process, having been used without methodological rigor for original or adapted instrument validation. This way, it's not possible to know - by these studies - if the tool really measures that which it proposes to measure.

On the other hand, one study was selected with the goal of validating the concurrent criterion of the Gaudenz-Fragebogen instrument, by its application in 1,938 Austrian women[1]. The results observed by these authors elicited similar conclusion obtained in the present study conducted with Brazilian women, i. e., the tool demonstrated low sensibility and specificity for the differential diagnosis of urinary incontinence[1].

### Concluding message

It can be concluded that the final version in Portuguese of the Gaudenz-Fragebogen, in the reliability assessment demonstrated to have satisfactory stability, homogeneity and equivalence. However, it wasn't capable of adequately discriminating the type of urinary incontinence when compared to the urodynamic study.

We consider that the adapted instrument is not recommended for use in Brazil as a single resource in female urinary incontinence diagnosis. However, we argue the importance of evaluating and re-evaluating the original or adapted instruments by different researchers, in distinct cultures and clinical situations, to compare its performance.

## References

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3. Oliveira LDR, Lopes MHB, Guirardello E B. Cultural adaptation of the Gaudenz Questionnaire for the diagnosis of urinary incontinence in Brazilian women. In: *Proceedings of the Joint Annual Meeting ICS/IUGA, 2010 Aug 23-27; Toronto, Canada.* Available in: <https://www.icsoffice.org/Abstracts/Publish/105/000957.pdf>

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Comitê de Ética em Pesquisa da Faculdade de Ciências Médicas da Universidade Estadual de Campinas (UNICAMP)
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes