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# Validation of the Brazilian version of the *Gaudenz-Fragebogen*: used in the differential diagnosis of female urinary incontinence

## *Validação da versão brasileira do Gaudenz-Fragebogen: utilizado para o diagnóstico diferencial da incontinência urinária feminina*

## *Validación de la versión brasileña del Gaudenz-Fragebogen: utilizado en el diagnóstico diferencial de la incontinencia urinaria femenina*

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## Abstract

**Objective:** To validate the Brazilian version of the *Gaudenz-Fragebogen* questionnaire, used in the differential diagnosis of female stress and urge urinary incontinence. **Methods:** Reliability was validated through the application of test-retest in 60 women. For the evaluation of the concurrent validity criterion, the diagnoses-based on the questionnaire's adapted scores-were compared to the urodynamic study (gold standard) in 116 women with urinary incontinence. **Results:** The questionnaire was found to be reliable and showed stability. The sensitivity and specificity for the diagnosis of stress urinary incontinence were 9.0% and 96.7%, and for urge urinary incontinence, 44.7% and 70% respectively. **Conclusion:** The questionnaire is reliable and stable, and it is suitable to be included in the phases that precede the final diagnosis. However, its use is not recommended as a single resource to determine the differential diagnosis of female urinary incontinence.

**Keywords:** Urinary incontinence; Diagnosis, differential; Validation studies; Women's health.

## Resumo

**Objetivo:** Validar a versão brasileira do *Gaudenz-Fragebogen*, utilizado no diagnóstico diferencial da incontinência urinária feminina de esforço e de urgência. **Métodos:** A confiabilidade foi conferida por meio da aplicação do teste-reteste em 60 mulheres. Para a avaliação da validade de critério concorrente os diagnósticos, baseados nos escores do questionário adaptado, foram comparados com o estudo urodinâmico (padrão-ouro), em 116 mulheres com incontinência urinária. **Resultados:** O questionário demonstrou ser confiável e apresentou estabilidade. A sensibilidade e especificidade para o diagnóstico da incontinência urinária de esforço foram 9,0% e 96,7%, e para a de urgência de 44,7% e 70%, respectivamente. **Conclusão:** O questionário é confiável e estável, e pode ser indicado para compor as fases que antecedem o diagnóstico final. Entretanto, não é recomendável a sua utilização como único recurso para determinar o diagnóstico diferencial da incontinência urinária feminina.

**Palavras-chave:** Incontinência urinária; Diagnóstico diferencial; Estudos de validação; Saúde da mulher.

## Resumen

**Objetivo:** Validar la versión brasileña del Gaudenz-Fragebogen, utilizado en el diagnóstico diferencial de incontinencia urinaria femenina de esfuerzo y urgencia. **Métodos:** La fiabilidad fue validada a través de la aplicación de teste-reteste en 60 mujeres. Para la evaluación del criterio de validez concurrente, los diagnósticos basados en puntajes del cuestionario adaptado, fueron comparados con el estudio urodinámico (patrón oro) en 116 mujeres con incontinencia urinaria. **Resultados:** El cuestionario demostró ser confiable y presentó estabilidad. La sensibilidad y especificidad para el diagnóstico de incontinencia urinaria de esfuerzo fueron 9,0% y 96,7%, y para la incontinencia urinaria de urgencia fueron 44,7% y 70%, respectivamente. **Conclusión:** El cuestionario es fiable y estable, y es adecuado para ser incluido en las fases que preceden diagnóstico final. Sin embargo, su uso no se recomienda como un único recurso para determinar el diagnóstico diferencial de la incontinencia urinaria femenina.

**Palabras clave:** Incontinencia urinaria; Diagnóstico diferencial; Estudios de Validación; Salud de la mujer.

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## INTRODUCTION

Urinary incontinence (UI) is a condition that affects women's quality of life negatively and it is defined as involuntary loss of urine[1]. In the female population, the three main types of UI are: stress urinary incontinence (SUI), urge urinary incontinence (UUI) and mixed urinary incontinence (MUI)[1]. Worldwide, prevalences of this health condition range from 10% to 55%, depending on the population studied and criterion used for the diagnosis, a fact that defines UI as a public health problem and, in this sense, deserving of greater attention[2].

Regarding the differential UI diagnosis, urodynamic testing (UDT) is considered to be the gold standard for the objective assessment of the lower urinary tract function, as it is regarded as the most efficient resource at present for the differential diagnosis of UI[3,4]. It is a set of tests that includes the following: analysis of free urinary flow, filling cystometry, pressure-flow analysis and urethral function assessment[5]. Although UDT is considered to be ideal for the objective assessment of the lower urinary tract function, it should not be recommended to all women with incontinence, especially in less complicated cases of UI[5].

Additionally, there are other factors that may prevent a greater availability of this test which should be taken into consideration. Urodynamic testing is restricted to specialized centers and it is a relatively expensive test, as it requires special equipment, trained professionals to perform and interpret it adequately[5]. A survey conducted by the City of São Paulo Court of Auditors showed that patients seeking the city's health care system wait for months or even years to schedule a test[6]. In the case of UDT, the waiting list is approximately 41 months and this has been the case for more than three years[6].

Due to several implications involved with the UDT implementation, especially in the Brazilian Unified Health System, known as SUS, it could be assumed that the use of specific instruments may subsidize the diagnostic process of UI[7]. A literature review found a specific instrument known as *Gaudenz-Fragebogen,* originally developed in German and validated to support the differential diagnosis of female SUI and UUI. This instrument was translated and adapted to the Brazilian culture and it was found to be easy to understand and be applied[7]. Furthermore, until now, it has been widely used by the scientific population in general and served to support clinical practice, mainly in European countries[8-10].

However, it is understood that the first stage of the study conducted with the Brazilian female population must be completed and, consequently, it is essential to submit the Portuguese version of *Gaudenz-Fragebogen* to the remaining stages of psychometric evaluation, after the translation and cultural adaptation of this instrument.

Thus, the present study aimed to assess the reliability and validity of the *Gaudenz-Fragebogen* version for the Brazilian context, so as to verify its performance as an instrument to measure the differential diagnosis of UI.

## METHODS

A methodological study with a quantitative approach was conducted, aiming to validate a specific instrument. This research project was approved by a Research Ethics Committee under official opinion 616/08.

Data were collected in the urodynamic assessment services of two outpatient clinics of the public health care network. One of these clinics belonged to a teaching hospital in the countryside of São Paulo state, aimed at caring for the community in general; the other belonged to a hospital that cared for women exclusively, located in the capital city of this state.

Women who went to the outpatient clinics to have UDT were invited to participate in this study. The research objectives, the right to withdraw one's consent of participation and the right to anonymity were explained to those who accepted to participate in this study. The informed consent form was described to them in detail and, upon their acceptance, this form was signed and they were subsequently interviewed. They completed the questionnaire so that social, demographic, clinical and obstetric characteristics could be obtained. Next, they received the *Gaudenz-Fragebogen* questionnaire and were informed about the fact that this instrument is self-administered, i.e. it would be read and completed by participants themselves. However, if they had any questions, they could ask the interviewer to answer any questions about this instrument. In addition to the researcher responsible for the study, two undergraduate students enrolled in the last semester of the nursing course were trained to help with data collection.

The *Gaudenz-Fragebogen* questionnaire is a measuring instrument comprised of 16 items, enabling two final scores: the Urge-score (U-S) for UUI; and the Stress score (S-S) for SUI. Each item has two alternatives, the first one corresponding to the S-S and the second to the U-S, while both score from zero to three for UUI or SUI. To achieve this, participants must select only one of the alternatives, i.e. that which best describes their current situation. The instrument's final score ranges from zero to 26 points both for the U-S and S-S[7].

In order to calculate the S-S, one (01) point is given to questions 1, 2, 4, 5, 11, 14 and 15; two (02) points to questions 3, 7, 8, 9, 10, 12, 13 and 16; and three (03) points to question 6. In contrast, to calculate the U-S, one (01) point is given to questions 1, 2, 3, 4, 11 and 14; two (02) to questions 6, 8, 13 and 15; three (03) points to questions 7, 9, 10 and 12; and zero (0) points to questions 5 and 16[7]. The cut-off points for this instrument were as follows: a U-S score between 13 and 26 and a S-S score between 0 and 6: positive diagnosis for UUI; a S-S score between 13 and 26 and U-S between 0 and 6: positive diagnosis for SUI[7].

The study sample was comprised of women who met the following inclusion criteria: to agree to participate in this study, to have complained about UI, to have undergone UDT recently, to be able to understand the instructions and to complete the specific questionnaire items. Women who had neurological

conditions and those who, during interview, had symptoms suggestive of urinary tract infection (UTI) or were undergoing UTI treatment were excluded from this study.

Sample size was calculated following this instrument's recommendation of ten participants per item[11]. Thus, the estimated sample totaled 160 women or more, as the *Gaudenz-Fragebogen* is comprised of 16 items.

In the first stage of verification of psychometric properties, a test-retest was performed aiming to observe the stability of the adapted instrument. The first 60 women who agreed to participate in this stage completed the *Gaudenz-Fragebogen* questionnaire two times, with an interval of seven days between the first and second application.

Women who participated in this stage were invited and informed that their participation was voluntary and, in case they changed their decision, this would not result in any changes to their treatment. Moreover, those who agreed to participate in the test-retest had their transport and food paid for in the second meeting.

Before responding to the questionnaire for the second time, participants were asked about the possibility of their having any UTI symptoms or using any drugs that they had not been using at the time of the first test. Only those who reported that neither of the situations applied to them were included in the test-retest.

The adapted instrument was submitted to concurrent criterion validity to verify the psychometric properties. For this stage, the medical reports on UDT were taken into consideration for the analysis, the gold standard for the present study whose diagnoses were UUI or SUI, as this instrument distinguishes between these two types of UI diagnosis. UDT was made available by the outpatient clinics and medical reports were transcribed by the researcher in charge on a file identified by the initials of participants' name and a control number, which were also found in both instruments previously completed.

Concurrent criterion validity was analyzed through the correlation coefficient between the type of UI identified by the *Gaudenz-Fragebogen* scores and the diagnosis described in the UDT medical report.

### Data analysis

The data obtained were analyzed using the SAS software, 9.1.3 version (SAS Institute Inc., Cary, NC, USA, 2002-2003). An analysis was performed with the description of the absolute and relative frequencies for the categorical variables and the description of the mean, standard deviation, median and maximum and minimum values for continuous variables, aiming to describe the sample profile.

The reliability of the Brazilian version of the *Gaudenz-Fragebogen* was assessed for its stability through the test-retest, considering the total scores of the first and second applications. To achieve this, the paired *T*-test and the Intraclass Correlation Coefficient (ICC) were performed to compare the means of scores.

Accuracy, sensitivity, specificity and the positive and negative predictive values of the Brazilian version of the *Gaudenz-Fragebogen* were determined through multiple comparisons among the UI groups identified by UDT and the instrument's scores, using analysis of variance (ANOVA).

The significance level adopted for the statistical tests was 5%, i.e. a $p$ value < 0.05 was taken into consideration.

## RESULTS

### Sample characteristics

A total of 168 women with complaints about involuntary loss of urine participated in the present study and they had a mean age of 53.6 years, ranging from 21 to 87 years of age. Participants' mean level of education was 6 years and that of family income was 2.4 monthly minimum wages. The majority of women, 161 (95.8%), had been pregnant and the number of pregnancies per woman varied from one to 24. There was a total of 700 births among participants, of which 627 (89.6%) were vaginal deliveries and 73 (10.4%) were Cesarean sections. A total of 65 women (38.7%) were found in the stage between menarche and menopause and 103 (61.3%) were in the post-menopausal stage, of which only eight (7.8%) were undergoing hormone replacement therapy. With regard to morbidities, systemic arterial hypertension stood out, as 40.5% of the sample had a chronic condition and 85% of them were using a certain type of diuretic.

### Reliability

The test-retest was applied to 60 women aged between 22 and 65 years and with a mean level of education of 5.8 years.

The stability of the adapted instrument had an Intraclass Correlation Coefficient (ICC) of 0.99 and a respective Confidence Interval (CI) of 0.95 for both scores. The means of both applications of the *Gaudenz-Fragebogen* questionnaire are shown in Table 1.

### Validity

A total of 116 medical reports of UDT, 78 cases of SUI (46.4%) and 38 of UUI (22.6%) were used for the adapted instrument's concurrent criterion validity. At this stage of the study, 34 cases (20.3%) of MUI and 18 (10.7%) without alterations, confirmed by the UDT, were ignored.

**Table 1.** Descriptive analysis of means of the Portuguese version of the *Gaudenz-Fragebogen* questionnaire in the test-retest (n = 60). Campinas, Brazil, 2010

| ***Gaudenz-Fragebogen* scores** | **Test** | **Retest** | ***p*-value$^{\delta\delta}$** |
|---|---|---|---|
| | **Mean (SD$^{\delta}$)** | **Mean (SD$^{\delta}$)** | |
| Stress score (SS) | 9.4 (5.3) | 9.4 (5.2) | 1.000 |
| Urge-score (US) | 16.7 (6.1) | 16.7 (6.0) | 0.821 |

$^{\delta}$ Standard deviation; $^{\delta\delta}$ Paired *t*-test.

The distribution of women who allegedly had urinary incontinence is shown in Table 2, indicating positive and negative cases of SUI and UUI, according to *Gaudenz-Fragebogen* scores and results of medical reports of UDT.

**Table 2.** Distribution of women with urinary incontinence, according to *Gaudenz-Fragebogen* scores and medical reports of UDT for the presence or absence of stress and urge urinary incontinence (n = 168). Campinas, Brazil, 2010

| *Gaudenz-Fragebogen* | UDT (Gold standard) | |
|---|---|---|
| | With SUI | Without SUI |
| With SUI | 7 | 3 |
| Without SUI | 71 | 87 |
| Total | 78 | 90 |
| | **With UUI** | **Without UUI** |
| With UUI | 17 | 39 |
| Without UUI | 21 | 91 |
| Total | 38 | 130 |

In the process of assessment of performance of the adapted instrument, the percentages of true-positive cases (sensitivity) was found to be 9.0% for SUI and 44.7% for UUI, whereas these percentages were 96.7% for SUI and 70% for UUI for true-negative cases (specificity) (Table 3).

**Table 3.** Performance of the *Gaudenz-Fragebogen* questionnaire for the diagnosis of stress and urge urinary incontinence (n = 116). Campinas, Brazil, 2010

| Diagnostic test | SUI | | UUI | |
|---|---|---|---|---|
| | % | 95% CI | % | 95% CI |
| Sensitivity | 9.0 | 3.7-17.6 | 44.7 | 28.6-61.7 |
| Specificity | 96.7 | 90.6-99.3 | 70.0 | 61.3-77.7 |
| Positive predictive value | 70.0 | 34.8-93.3 | 30.4 | 18.8-44.1 |
| Negative predictive value | 55.1 | 47.0-63.0 | 81.3 | 72.8-88.0 |
| Accuracy | 56.0 | 48.2-63.7 | 64.3 | 55.4-73.2 |

## DISCUSSION

The population sample, mainly comprised of women with a low level of education, resulted in certain limitations regarding the self-administration of the instrument used in this study, when at times participants needed to be helped to read and understand its questions. However, through the interviewer's intervention, the items comprising this instrument were easily understood and responded by participants, as the questions were simple and objective, clearly focusing on recurrent situations experienced by women with urinary incontinence.

Currently, the use of specific questionnaires is an increasingly recurrent practice in the screening process of diagnoses and, consequently, it supports decision-making in health. However, this needs to take place in a safe way and, consequently, a measuring instrument has to perform well in terms of reproducibility in different situations and efficiency to measure that which is designed to measure.

Regarding reliability, it can be affirmed that the Brazilian version showed good reproducibility as a result of the test-retest; moreover, that a general or specific instrument with an ICC above 0.90 is reliable[12], as it led to similar results, even when applied under different circumstances[13].

A certain instrument can be considered as valid, even with low reliability; nonetheless, it can have high reliability without any validity[12]. Consequently, it will be regarded as valid in the sense that it measures that which it is designed to measure[12]. Thus, a specific questionnaire such as the *Gaudenz-Fragebogen* has more value if it allows for more sensitivity rather than specificity, when compared to the gold standard. For this reason, the Brazilian version of the *Gaudenz-Fragebogen* questionnaire was expected to show more sensitivity, so that a differential diagnosis could be determined.

A study conducted with Polish women had its original instrument validated with other specific questionnaires and although it allowed for high sensitivity, it did not show good specificity, as it did not provide sufficient information for the differential diagnosis between SUI and UUI[14]. In other words, the scores identified UI, but did not adequately distinguish the type when submitted to concurrent criterion validity.

Although results similar to those from the Polish study have been observed in the validity of the adapted version of this instrument, it should be emphasized that all participants reported their involuntary loss of urine and the resulting negative impact on their quality of life. Additionally, although 18 cases without alterations were found through UDT, this does not necessarily imply the unconditional absence of UI. Although UDT is the most accurate test available to identify and differentiate UI at present, it is safe to consider these 18 cases to be normal as, objectively, no loss of urine due to stress or uninhibited contractions of the detrusor muscle were observed during testing, conditions that guide the diagnosis of SUI and UUI, respectively.

It should also be emphasized that UDT is recommended in more complex cases of UI in Brazil, as it is restricted to specialized centers and relatively expensive[5]. Additionally, there is the fact that even in areas where socioeconomic conditions are better, the waiting list for women to have UDT in the public health system can be longer than three years[6]. Nonetheless, UI is regarded as relevant in epidemiological terms, although ignored by public policies, professional educational organizations and, consequently, clinical evaluation and interventions[15].

In view of what has been described, it is worth noting that the *Gaudenz-Fragebogen* questionnaire has been widely used since its creation in German-speaking countries and health professionals consider it to be a benchmark in the screening process prior to female UI diagnosis, especially as there has been an increase in the number of cases[16]. The relevance of

this instrument is associated with its practicality, enabling it to be used at the moment of anamnesis, and its ability to detect the characteristics of patients' complaints and suffering in detail[8]. Moreover, this instrument is useful to qualitatively distinguish between SUI, which is supposedly present, and UUI[8]. Thus, its use is recommended as part of the stages followed before the final diagnosis[8].

Safe levels of agreement between the Brazilian version of the *Gaudenz-Fragebogen* and UDT are expected to be found in the present study, so that its use can be recommended in the differential diagnosis of UI of Brazilian women, thus providing quantitative and qualitative support in the current context. However, in order to guarantee the legitimacy of the results measured with a diagnostic validity instrument, it is essential that its performance be similar to the gold standard.

Although the results obtained in the present validation study were not completely satisfactory, it is agreed that the original or adapted instruments must be used by other researchers in new groups and situations, as this enables the performance of such instruments to be observed and compared in different contexts.

## CONCLUSION

The Portuguese version of the *Gaudenz-Fragebogen* questionnaire was found to be reliable and it showed stability. However, based on the way this instrument performed in the present study, it is not recommended as the only resource for the conclusive validation of differential diagnosis between SUI and UUI.

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