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COMPARATIVE STUDY BETWEEN BLADDER DIARY AND URODYNAMIC STUDY TO IDENTIFY LOWER URINARY TRACT SYMPTOMS

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ABSTRACT

Objective: To identify the similarity of lower urinary tract symptoms presented in the urodynamic study compared to the urinary diary. **Method:** This is a comparative study carried out in an urodynamics clinic in southern Santa Catarina, Brazil, with 44 patients who underwent the examination. Data collection was carried out by applying a questionnaire and a 72-hour bladder diary and comparing it with the findings of the urodynamic study using the SPSS for Windows and Stata/SE v.14.1 programs. **Results:** The bladder diary showed high specificity, sensitivity, and accuracy for identifying detrusor hyperactivity and stress urinary incontinence. There was no difference for bladder capacity (p* 0.198). It pointed to bladder sensitivity with a volume smaller than that presented by the urodynamic study (p*<0.001). It was able to identify lower urinary tract symptoms that were not present in the urodynamic study. **Conclusion:** The bladder diary was effective for identifying lower urinary tract symptoms and can be used to define first-line treatment with a broader range of population diagnosis, shorter time between complaints and treatment, cost reduction for the system, and less discomfort for the patient.

DESCRIPTORS: Lower urinary tract symptoms. Urinary incontinence. Urinary retention. Nursing. Enterostomal therapy.

ESTUDO COMPARATIVO ENTRE DIÁRIO VESICAL E ESTUDO URODINÂMICO PARA IDENTIFICAÇÃO DE SINTOMAS DO TRATO URINÁRIO INFERIOR

RESUMO

Objetivo: Avaliar a efetividade do diário vesical para identificar sintomas do trato urinário inferior, em comparação ao estudo urodinâmico. **Método:** Trata-se de estudo observacional de corte transversal realizado em uma clínica de urodinâmica do sul catarinense com 44 pacientes submetidos ao exame. A coleta de dados deu-se por aplicação de questionário de dados epidemiológicos e de sintomas e diário vesical de 72 horas e comparação deste com os achados do estudo urodinâmico por meio do programa Stata/SE v.14.1. **Resultados:** O diário vesical apresentou alta especificidade, sensibilidade e acurácia para identificação de hiperatividade detrusora e incontinência urinária de esforço. Não apresentou diferença para capacidade vesical (p* 0,198) e apontou sensibilidade vesical com volume menor do que o apresentado pelo estudo urodinâmico (p*<0,001). Foi capaz de identificar sintomas de trato urinário inferior que não haviam se revelado no estudo urodinâmico. **Conclusão:** O diário vesical mostrou-se tão efetivo quanto o estudo urodinâmico para identificação de sintomas de trato urinário inferior, podendo ser utilizado para definição de tratamento de primeira linha com maior abrangência de diagnóstico populacional, menor tempo entre queixa e tratamento, redução de custo para o sistema e menor desconforto para o paciente.

DESCRITORES: Sintomas do trato urinário inferior. Incontinência urinária. Retenção urinária. Enfermagem. Estomaterapia.

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ESTUDIO COMPARATIVO ENTRE EL DIARIO VESICAL Y EL ESTUDIO URODINÁMICO PARA IDENTIFICAR LOS SÍNTOMAS DEL TRACTO URINARIO INFERIOR

RESUMEN

Objetivo: Evaluar la efectividad del diario vesical para identificar síntomas del tracto urinario inferior, en comparación con el estudio urodinámico. **Método:** estudio observacional de corte transversal realizado en una clínica de urodinamia en la región sur del estado de Santa Catarina (Brasil) con 44 pacientes sometidos al examen. La recolección de datos fue realizada por medio de la aplicación de cuestionario de datos epidemiológicos, caracterización de síntomas y diário vesical de 72 horas. La comparación entre los mismos y los hallazgos del estudio urodinámico fue realizada por medio del programa Stata/SE v.14.1. **Resultados:** el diario vesical presentó alta especificidad, sensibilidad y validez para la identificación de la hiperactividad detrusora y de la incontinencia urinaria de esfuerzo. No hubo diferencia en la capacidad vesical (p* 0,198), el diario vesical indentificó sensibilidad vesical con un volumen menor que el presentado por el estudio urodinámico (p*<0,001). El diário fue capaz de identificar síntomas del tracto urinario inferior que no fueron revelados en el estudio urodinámico. **Conclusión:** el diario vesical se mostró tan efectivo como el estudio urodinámico para la identificación de síntomas del tracto urinario inferior, con gran potencial de ser utilizado para definición de tratamiento de primera linea con mayor cobertura de diagnóstico poblacional, menor tiempo entre la queja y el tratamiento, reducción de costo para el sistema de salud y menor incomodidad para el paciente.

DESCRIPTORES: Síntomas del tracto urinario inferior. Incontinencia urinaria. Retención urinaria. Enfermería. Estomaterapia.

INTRODUCTION

Approximately 40% of the world population suffers from urinary dysfunction, either manifested by incontinence or by urinary retention. Urinary incontinence (UI) leads to psychoemotional conditions, social isolation, low labor productivity, low quality of life, and is associated with falls and increased mortality in the elderly. Urinary retention increases the risk of urinary tract infection (UTI) and upper urinary tract dysfunction[1-4].

A careful evaluation of the person with voiding dysfunction is determinant for obtaining good results in the therapeutic approach. The need for anamnesis and targeted physical examination is undeniable, but a deeper investigation of the voiding pattern is necessary. A worldwide established method for this investigation is the urodynamic study (UDS)[5].

The UDS is an invasive test that helps to identify lower urinary tract symptoms (LUTS) by simulating the bladder filling and emptying phases for evaluation[6]. The exam involves free uroflowmetry, cystometry, pressure flow study and some include urethral function tests and electromyography[7-9].

Despite the undeniable contributions presented by the UDS for the therapeutic management of voiding dysfunctions, its performance in the current standards involves physical and emotional discomfort, besides resulting in high cost and presenting variable diagnostic accuracy, due to the artificiality of the use of catheters and rapid retrograde filling of the bladder[7,10,11].

Because of the high cost to the health care system and the long waiting lines for the exam, many patients begin treatment without it. The authors of this study often accompany patients in their clinical practice who are treated until they are discharged from the hospital without undergoing the test. Thus, the question is how necessary it is as a first line of investigation. Recent studies point to excessive use of UDS in clinical conditions where it brings little contribution, even after consistent studies have demonstrated these results[12,13].

A conservative and low-cost way to assess urinary pattern and symptoms is the bladder diary (BD), a noninvasive tool used to assess bladder sensations on a daily basis. Besides urinary frequency and volume, it also includes the degree of desire and the perception of the fullness of the bladder before emptying, and is considered an important tool for the diagnosis of voiding dysfunction[14]. This instrument is filled out by the patients themselves or by a caregiver and can be oriented by any health professional who works with people who present with urinary complaints.

In this context, it is worth mentioning that nurses are supported by their federal council[15] to act in the conservative treatment of micturition dysfunctions. Thus, as the professionals are present at all levels of health care, they can investigate the first line of treatment and act on it, enabling resolution of cases in primary care and referral of complex or refractory cases[16].

Given the problem presented, this study aimed to evaluate the effectiveness of the BD to identify the LUTS, compared to the UDS. It was assumed that the BD is capable of identifying most of the symptoms presented in the UDS, and thus can be used for evaluation and therapeutic guidance in patients in the initial approach.

METHODS

This is an observational, cross-sectional study[17]. The research was conducted in a urology clinic located in southern Santa Catarina state, Brazil. An average of 60 UDS are performed monthly in patients seen by the Unified Health System (UHS), some health insurance companies, or privately.

Data collection occurred in April 2020. The sample was composed of convenience patients referred for the UDS during the data collection period. All patients referred for the exam were invited to participate in the research, based on the following eligibility criteria: being over 18 years old, being literate, having a medical referral for the exam, and answering the questions in a questionnaire. The patients were approached regarding the research when they went to the clinic to schedule the exam or directly for its performance, having made the appointment by phone.

Data collection was done by applying a questionnaire with general epidemiological data and symptoms and by analyzing the completed BD and the UDS charts and reports. The questionnaire was filled out by the main researcher of the study, who also made a simulated filling out of some lines of a diary, in order to facilitate the patients' understanding for the subsequent filling out.

Patients who scheduled the UDS on site received the BD and returned it completed on the day of the exam. Patients who scheduled the exam by phone were informed of the survey on the day of the exam, received the BD on the same day, and had up to seven days to complete and return it. Patients who did not return the completed BD were part of this second group.

For data analysis, a Microsoft Excel spreadsheet was built to extract the following variables: bladder sensitivity; maximum cystometric capacity (defined as bladder capacity when not identified through the UDS); detrusor overactivity (defined as overactive bladder when its identification is not based on the UDS); urinary loss during detrusor overactivity (DO); urinary loss on stress; and urinary retention. All this information is in the UDS report and can also be identified in the graph generated during the exam.

The extraction of the same variables by means of the BD (table recording urinary times and volumes and urinary symptoms in the 24 hours, for three days) was done based on the definition of LUTS described by the International Continence Society (ICS)9. Bladder sensitivity was defined as the smallest urinary volume that led to micturition urge. Bladder capacity was considered by the largest volume urinated in the three days of filling. The evaluation of overactive bladder was performed by the presence of symptoms such as urgency to urinate, increased frequency and/or nocturia, which may manifest with (wet) or without (dry) UTI. The urinary loss on effort was considered when there was loss in some activity with increased abdominal pressure. Urinary retention was considered when the volume ingested was greater than that eliminated, besides the sensation of incomplete emptying.

After coding and organizing the data, they were statistically analyzed using the Stata/SE v.14.1 program, for presentation of descriptive data and cross-referencing between the evaluation instruments. The results of quantitative variables were described by mean, standard deviation, minimum, and maximum. The normality condition of these variables was assessed by the Kolmogorov–Smirnov test. For categorical variables, frequency and percentage were presented. To evaluate the quality of the BD in predicting the outcome of the UDS (gold standard), the indices of sensitivity, specificity, and accuracy were estimated. The positive and negative predictive values were also presented considering prevalence estimated by the study sample. This analysis was performed taking into account the presence

or absence of DO, urinary loss during DO, stress urinary loss and urinary retention. BD sensitivity was defined as the probability that the BD result is present given that the UDS result is present, and BD specificity as the probability that the BD result is absent given that the UDS result is absent. Probability of false positive is the probability that the BD result is present given that the UDS result is absent (1: specificity), and probability of false negative is the probability that the BD result is absent given that the UDS result is present (1: sensitivity). Accuracy is the overall hit probability of the BD. Positive predictive value is the probability that the UDS result is present, given that the BD result is present, and negative predictive value is the probability that the UDS result is absent, given that the BD result is absent[1].

Student's t-test for paired samples was used to compare the BD and UDS results in relation to the variables. The bias of the BD results relative to the UDS were presented in scatterplots and Bland- Altman diagrams. Values of $p < 0.05$ indicated statistical significance. Data were analyzed with the Stata/SE v.14.1 computer program.

All participants signed the free and informed consent form, and the confidentiality of identity and all other requirements contained in Resolution No. 466/12 of the National Health Council were preserved. The research was approved by the Ethics Committee for Research with Human Beings (Approval No. 3,939,142).

RESULTS

Of the 50 patients invited to participate in the study, 44 delivered the questionnaire and the BD. The mean age of the participants was 52.5 years (standard deviation, SD = 13.3), ranging from 24 to 86 years. They were 95.5% female.

Table 1 presents the sensitivity, specificity, accuracy and predictive value of BD when compared to UDS, for the findings of DO, UI during DO, stress UI (SUI) and urinary retention. The evaluation of sensitivity and positive predictive value of urinary retention was impaired by the low number of patients with this symptom present (n = 2). The specificity of the BD in the loss on effort was 70%. For all other results, the sensitivity, specificity and accuracy were higher than 84%, demonstrating a high positive and negative predictive capacity of the BD for the variables analyzed.

Table 1. Predictive ability of urinary symptoms presented in the urodynamic study by bladder diary. Santa Catarina, 2020.

Variable	Sensitivity (%)	Specificity (%)	Accuracy (%)	FP+ (%)	FP– (%)	PV+ (%)	PV– (%)
Detrusor overactivity	88.9	85.7	86.4	14.3	11.1	61.5	96.8
Urinary loss during detrusor hyperactivity	100	92.1	93.2	7.9	0	66.7	100
Stress urinary loss	95.8	70	4.1	30	4.2	79.3	93.3
Urinary retention	-	100	100	0	-	-	100

FP+: probability of false positive; FP–: probability of false negative; PV+: positive predictive value; PV–: negative predictive value. Source: Elaborated by the authors.

Nine patients presented with DO. Of these, eight were identified by BD. Another five patients had suspected DO by the BD, which was not confirmed by the UDS. All six cases of urinary loss during DO presented in the UDS were predicted by the BD, but another three were suspected and not confirmed.

Similar behavior was seen in SUI. The UDS identified 24 patients. Of these, 23 were predicted at the BD. Six other patients presented SUI only on the BD. Only two patients had urinary retention by the UDS, both identified also on the BD.

Figure 1 shows the results for bladder sensitivity (mL) and bladder capacity (mL). Each point corresponds to a patient's UDS (horizontal axis) and BD (vertical axis) results. The red line represents points for which the two results are equal.

Below it are the cases where the BD was lower than the UDS and above it the cases where the BD was higher than the UDS. It can be seen that there is a predominance of cases with BD lower than UDS; however, there is a tendency for the two results to be constantly closer together.

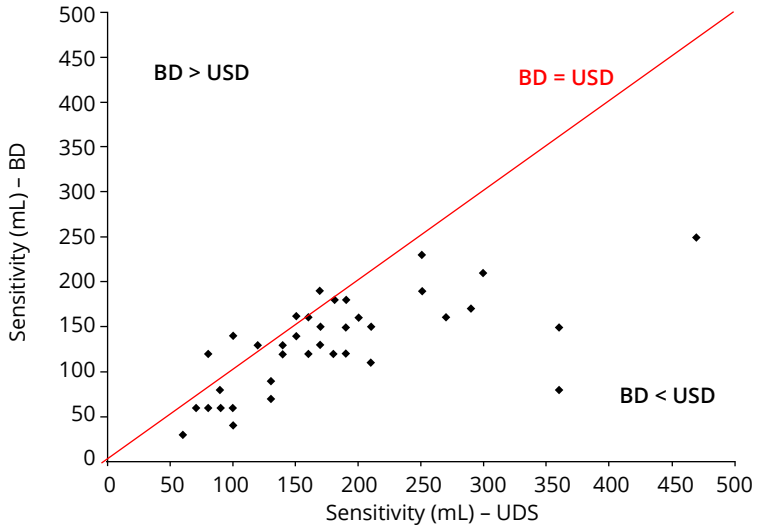

Figure 1. Scatter plot for bladder sensitivity presented by urodynamic study (UDS) and bladder diary (BD). Santa Catarina, 2020.

Source: Elaborated by the authors.

The results showed a significant difference between UDS and BD regarding the sensitivity value (UDS: mean = 182.3, SD = 86.3; BD: mean = 134.3, SD = 52; mean difference 48 mL; $p < 0.001$), demonstrating that, from the BD, there is a tendency to interpret that the patient's sensitivity is higher, with an awakening of micturition desire with 48 mL less than in the UDS.

Figure 2 demonstrates the evaluation of bladder capacity parameters. No significant difference was found between UDS and BD (UDS: mean = 391.7, SD = 75.4; BD: mean = 382.7, SD = 74.3; mean difference = 9; $p = 0.198$), demonstrating that the BD can predict the actual capacity found in the UDS.

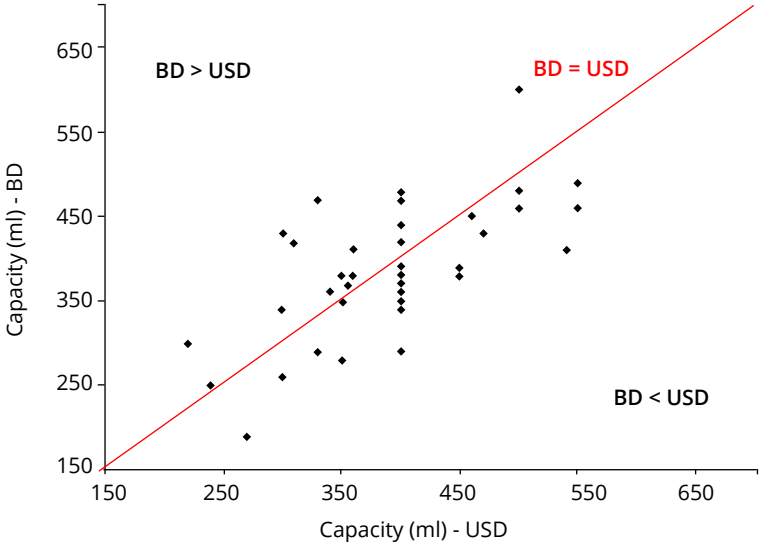

Figure 2. Scatter plot for bladder capacity presented by urodynamic study (UDS) and bladder diary (BD). Santa Catarina, 2020.

Source: Elaborated by the authors.

DISCUSSION

The BD showed high specificity, sensitivity and accuracy to identify DO and SUI. It showed no difference for bladder capacity, but pointed bladder sensitivity with lower volume than the UDS and was able to identify LUTS that did not present in the UDS.

The mean age of the participants, as well as the range between minimum and maximum age, converges with the literature, which points to the prevalence of LUTS at all ages. The predominance of women is also widely documented by the various risk factors, such as gestational history, hysterectomy, constipation, and menopause[3,18-20]. A European study demonstrated 24% overall prevalence of UTI in women and 7% in men, increasing with age to 50 and 29%, respectively[20].

Only one patient who presented with DO at UDS had not been considered with overactive bladder by BD. The DO is demonstrated by detrusor contraction in the bladder filling phase, in which there is elevation of detrusor and bladder pressure, without abdominal pressure changes associated with the desire to urinate or not[9]. When identified by the clinic, without confirmation by the UDS, it is called overactive bladder. Patients with DO or overactive bladder had a greater perception of fullness and urgency for the same volume urinated when compared to healthy volunteers[14], so that these patients have less bladder capacity[21]. It is noteworthy that at least five other patients had suspected DO, which was not confirmed. This data can be thought of as a false positive or interpreted as that the BD has a greater ability to identify symptoms because it represents more physiologically the 72-hour context, while the UDS is influenced by physical and emotional discomfort, retrograde infusion of solution, presence of catheters and temperature changes[7].

A recent study used medical records of 623 women with DO who underwent 3-day BD and underwent UDS. The conclusion was that DO patients have episodes of frequent voiding urgency and that dry and wet DO have differences between clinical and UDS data[21]: a poor congruence between clinical assessment and UDS occurs, being more evident in the group of patients with a clinical diagnosis of overactive bladder[22].

Only one patient who lost urine on exertion during the UDS had not been identified by the BD as having SUI. On the other hand, six patients had loss on exertion when the BD was filled out and did not present it during the UDS, again demonstrating the ability of the BD to capture symptoms that may not manifest themselves during the period of the exam. Some authors suggest that there is a weak correlation between the clinical diagnosis for UI and the urodynamic results. They mention that the UDS is not a completely reliable method and that it cannot provide a definitive diagnosis, requiring an evaluation based on clinical findings, the BD, the physical examination and a careful interpretation of the test data[22].

The most prevalent micturition dysfunction is SUI. Despite its impact on quality of life, it is underdiagnosed for several reasons[20]. Epidemiological data show that SUI is the most common micturition dysfunction and should be seen as a public health problem, since it may affect 20 to 50% of women worldwide at some stage of their lives[18].

In a retrospective study of 116 women with symptoms of UI, the UDS was compared with the clinical diagnosis of each patient. In 69 women, the clinical diagnosis was not confirmed by UDS. Only 38% of the cases were confirmed by the UDS. Thus, the agreement between the UDS and the clinical evaluation in the identification of the type of UI is low[22].

Urinary retention was demonstrated equally in the UDS and BD. In the UDS it is evaluated by the postmicturition residue collected at the bladder catheterization after free uroflowmetry and by the comparison of infused and urine volume at the end of the exam[9]. When assessing bladder sensitivity, the results of this study showed a difference of –48 mL, with greater sensitivity indicated in the BD. In UDS the sensitivity would be the first urge to urinate, which should occur with the infusion of one third of the maximum cystometric capacity (highest volume tolerated without discomfort).

Normal bladder filling sensation or sensation is defined by the ICS when the person is aware of the filling of the bladder and the increase of sensation, until the strong urge to urinate[9]. The UDS is the standard technique for assessing bladder sensation[23], but the BD has shown good reliability for assessing this data[24], since the UDS does not reproduce the behavior of the bladder during daily life, as bladder filling is a continuous and increasing perception[25].

For bladder capacity, no significant difference was found between UDS and BD. In UDS, bladder capacity is the bladder volume that brings the patient to the strong urge to urinate, without being able to delay. The ICS defines maximum

cystometric capacity as when the patient can no longer delay urination[9]. In the present study the highest capacities found were 550 and 600 mL, of the UDS and BD, respectively.

Still regarding bladder capacity, authors state that each patient has specific situations and that one cannot compare bladder capacity as a whole. They also say that the physical examination is not always conclusive, requiring the UDS or BD[26]. A 2020 study pointed out that DO patients have lower bladder capacity, ranging from 240 to 280 mL[21]. Another study evaluated UDS of patients submitted to surgical repair of pelvic organ prolapse and observed increased bladder capacity (greater than 600 mL) associated with incomplete emptying[27].

The good practice guidelines for performing the UDS, published by the ICS in 2018, indicate completing the BD for three days prior to the exam as part of the protocol[8]. The predictive ability indicated in this study and the superiority in detecting LUTS point to the possibility of BD being used on its own for first-line treatment setting, and not just as a preparation for UDS. A recent publication compared the satisfaction of women treated based on UDS findings and women treated based on a UI impact assessment questionnaire. A total of 680 women were included in the study, of whom 202 refused to undergo the examination and were conducted as a control group, treated based on the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) instrument. At the end of three months follow-up, the overall satisfaction rate of patients in group 1 and group 2 was 77 and 65.8%, respectively ($p = 0.003$)[28].

The VALUE study (multicenter randomized controlled trial) published in 2012 demonstrated that performing UDS does not change the post-surgical outcomes of women with uncomplicated SUI with an indication for sling. Currently researchers have sought to investigate whether after this publication the performance of the exam has reduced in such patients. A study conducted in a clinic in Ohio, USA, pointed to a reduction from 70 to 44% ($p < 0.00001$)[13]. Another study, conducted in Virginia, United States, observed a decrease in the rates of the exam in the mentioned preoperative periods from 68 to 58% ($p < 0.001$). Despite the statistically significant decrease in indications for UDS in patients with uncomplicated SUI who would undergo surgery for sling implantation, a high percentage of indication was still seen, in view of the cost and discomfort of the test and the finding that it would not change the therapeutic outcome[12].

In addition to discomfort and costs, pain and anxiety about performing the UDS also appeared in a study conducted in Turkey, in which researchers evaluated the effects of music therapy in reducing these variables during the examination. The reduction in pain and anxiety was not statistically significant, but the use of music therapy increased patients' willingness to perform the procedure again should the need arise[10]. A Korean study also cites pain, anxiety, and distress during the exam, investigating the effects of a heated pillow in the sacral region during the procedure, which in this case was effective in reducing these factors[11].

As a limitation of the study, it is worth mentioning the size of the sample, possible due to the restricted period of time for data collection, but the rates found for each symptom are in line with prevalence data widely published in the literature of the area. The predominantly female sample may limit the generalization of the results, but it coincides with the prevalence of LUTS when compared between genders.

It is expected that this work will contribute to the motivation to use the BD for all patients complaining of bladder storage or emptying symptoms and to the definition of first-line therapeutic management. Such a change will allow nurses to act as agents of investigation and treatment, significantly increasing the number of people seen, reducing queues and costs to the health system. As a possibility for future studies, the authors suggest studies that evaluate the therapeutic result of conducts based on the findings of BD and clinical evaluation.

CONCLUSION

The BD showed high specificity, sensitivity and accuracy for identification of DO with or without urinary loss and SUI when compared to the UDS. It did not present a statistically significant difference for bladder capacity, but pointed to bladder sensitivity with a smaller volume than that presented by the UDS.

The BD was able to identify LUTS that did not present in the UDS, appearing to be superior for identifying DO and SUI.

AUTHOR CONTRIBUTION

Substantive scientific and intellectual contributions to the study: Assis GM, Salvador MB and Olandoski M; **Conception and design:** Assis GM and Salvador MB; **Data collection, analysis and interpretation:** Assis GM, Salvador MB and Olandoski M; **Article writing:** Assis GM and Salvador MB; **Critical revision:** Assis GM and Olandoski M; **Final approval:** Assis GM and Olandoski M.

AVAILABILITY OF RESEARCH DATA

All data were generated or analyzed in the present study.

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