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GENERAL GYNECOLOGY

Gabapentin for the management of chronic pelvic pain in women

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Abstract

Background Chronic pelvic pain (CPP) is a frequent presenting symptom in gynaecology outpatient clinics. Neuromodulator pharmacological agents could be an option for treatment based on its efficacy in treating chronic pain in other conditions.

Purpose This study aimed at evaluating the efficacy of oral Gabapentin to alleviate pain in women with CPP.

Methods In a randomized double-blinded placebo-controlled trial, 60 women suffering from chronic pelvic pain were randomly divided into two equal arms. The study group received Gabapentin 300 mg three times daily initially (900 mg), with 300 mg weekly incremental dose till pain was controlled, severe side effects occurred or maximum daily dose of 2700 mg was reached. The Primary outcome was the pain score improvement of CPP, defined as a 30% reduction in the pain score assessed by the 10-cm Visual Analogue Scale compared to baseline score.

Results In Gabapentin group, pain was significantly reduced at 12 and 24 weeks (mean = 5.12 ± 0.67 and 3.72 ± 0.69, respectively) than in placebo group (mean = 5.9 ± 0.92 and 5.5 ± 1.13, respectively); this difference was significant. At 24 weeks, there was significantly higher proportion of patients reporting 30% or more reduction in pain scores; 19 out of 20 patients (95%) in Gabapentin group compared to 8 out of 14 patients (57.1%) in placebo group. The relative risk for pain after gabapentin treatment was 0.5 with 95% confidence interval = 0.34 to 0.75 and number needed to treat = 3 ($p = 0.007$). Regarding adverse effects there was significantly higher incidence of dizziness with Gabapentin (26.1%) compared to placebo (3.3%).

Conclusion Chronic pelvic pain in women may be treated sufficiently with Gabapentin.

Trial registration The trial was registered in ClinicalTrials.gov registry with clinical trial registration number: NCT02918760.

Keywords Chronic pelvic pain · Gabapentin · Visual analogue scale · Chronic pain · VAS

Introduction

Chronic pelvic pain (CPP) is a frequent presenting symptom that may have a great impact on quality of life. Currently there is no consensus on its definition: the Royal College of Obstetrician and Gynecologists defined CPP as "intermittent or constant pain in the lower abdomen or pelvis of a woman of at least 6 months in duration, not occurring exclusively with menstruation or intercourse and not associated with pregnancy" [1], while the American College of Obstetrician and Gynecologists defined CPP as "noncyclic pain that lasts 6 months or more; is localized to the pelvis, the anterior abdominal wall at or below the umbilicus, or the buttocks; and is of sufficient severity to cause functional disability or require medical care [2].

CPP in women may have a wide range of contributing etiologies with interacting psychological factors, which leads to a complex condition commonly difficult to confront by the patients and their care providers. Several pathologies may contribute to CPP including gynecological, urological and gastrointestinal conditions as well as musculoskeletal and neurological factors [3].

Inflammatory and autoimmune mechanisms have been postulated in the pathogenesis of CPP [4] but due to the wide range of listed etiology there is still no agreed mechanism for CPP. Being multifactorial in origin, the pathophysiology of CPP is suggested to share a common final pathway in the form of inflammatory or neurogenic insult, which finally manifests as chronic pain [5].

Several medical and surgical modalities for management of CPP that have been published with no definite cure could

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be attributed to any. First line pharmacological treatment included analgesics up to opioids, hormonal and ovarian suppression. Neuromodulators have been proposed for CPP management including Amitriptyline [6], Nor-triptyline [7], Pregabalin [8] and Gabapentin [6, 9]. This suggestion is based on good evidence available on its efficacy in managing chronic pain in certain conditions [10, 11].

Gabapentin (1-aminomethyl cyclo-hexanacetic acid) is structural analogue of γ-amino butyric acid (GABA); although it has no direct effect on GABA, it has namely two actions: inhibiting voltage-gated calcium channels and increasing the availability of GABA [12]. The mechanism of Gabapentin to treat neuropathic pain is still unknown. The most accepted theories are *N*-methyl-D-aspartate receptor antagonism and calcium channel blocking [13]. It has also been reported that ectopic discharge from injured peripheral nerves could be inhibited by Gabapentin [14]. The aim of the present work was to evaluate the efficacy of oral Gabapentin to alleviate pain in women with idiopathic chronic pelvic pain confirmed by negative laparoscopic finding.

Materials and methods

This was a double-blinded placebo-controlled randomized clinical trial. The trial was registered in ClinicalTrials.gov registry. Trial registration number: NCT02918760. The study was carried out at Ain Shams University, Cairo, Egypt between March 2016 and March 2018. The study protocol was in agreement with the Helsinki declaration of the Principles of Ethical Medical Research [last updated in Brazil 2013]. The Ethical Medical Committee of Obstetrics and Gynecology Department, Ain Shams University, had approved the study protocol.

All women who attended the gynecology outpatient clinic during this period complaining of CPP were approached and VAS pain score sheets were distributed to all potential participants and they were asked to fill them after obtaining their initial consent. Potential candidates were counselled about the study and a leaflet was handed to each woman which thoroughly explained the purpose and procedure of the study and relevant data about the study hypothesis and the available alternatives for management of CPP. And they were scheduled for a return visit within 7 days when they met the primary investigator who counselled the women again and then obtained the written consent. Those women who met the inclusion criteria have been randomized.

Inclusion criteria included (a) women aged between 25 and 45 years; (b) women with moderate to severe chronic pelvic pain of > 6 months' duration, not occurring exclusively with menstruation or intercourse and not associated with pregnancy; (c) women whose chronic pelvic pain had been incompletely relieved by non-steroidal anti-inflammatory drugs (NSAIDs); (d) No obvious pelvic pathology (e.g. endometriosis, adhesions, ovarian cysts… etc.) detected by laparoscopy (Laparoscopy should have been performed no more than 12 months before enrolment); (e) women should use and continue to use effective contraceptive method to avoid pregnancy. Moderate pain was defined as VAS score of 4–6 and severe pain was defined as VAS score of 7 or more [15].

Exclusion Criteria included (a) suspected or known pregnancy or planning for pregnancy in the coming 6 months; (b) breast-feeding; (c) active pelvic infection; (d) Known hypersensitivity to Gabapentin; (e) previous diagnosis of endometriosis/adhesions confirmed by laparoscopy ;(f) chronic or recurrent gastrointestinal disease including irritable bowel syndrome; (g) severe renal or hepatic impairment; (h) previous diagnosis of malignancy; (i) chronic alcohol use and (j) tranquilizer use.

All participating women had to sign an informed written consent after thorough explanation of the purpose and procedure of the study. 103 Patients have been approached, 39 patients have been excluded being not fulfilling the inclusion/ exclusion criteria of the study and the remaining 64 participants have been recruited to the study. During initial work up of the study, four patients changed their mind about the desire for planning pregnancy in the upcoming 6 months, so they were excluded from all data analysis. The remaining 60 women fulfilled the required sample size and had been randomized (Fig. 1).

Randomization was performed using a computer-generated randomization system (SPSS Random Number Generator; SPSS Inc., Chicago, USA) using randomization sequence 1:1 ratio. Computer generated randomization cards were produced and kept in the hospital pharmacy to prepare packages and provide supply and resupply. The package contents were kept unknown to the physicians, nurses and participants.

After randomization, a trial pack from the hospital pharmacy containing either Gabapentin or placebo oral tablets, both of identical appearance, was given to participants. Placebo tablets were identical to Gabapentin tablets and were manufactured by the same company. Both the participants and the research team were blinded to allocation. Participants started on oral Gabapentin (Gaptin® 300 mg capsules, Delta Pharma) at an initial dose of 900 mg per day (divided in three doses). The dose has been increased by one capsule 300 mg on weekly basis (with a maximum dose of 2700 mg per day) until sufficient pain relief was achieved, or the development of adverse effects such as dizziness, somnolence, edema, or ataxia. Women were followed up weekly at the outpatient clinic for 6 weeks to adjust dose and check for any adverse effects. Participants were asked to keep a diary of any adverse events and to contact the research team if they have any event that required them to be hospitalized.

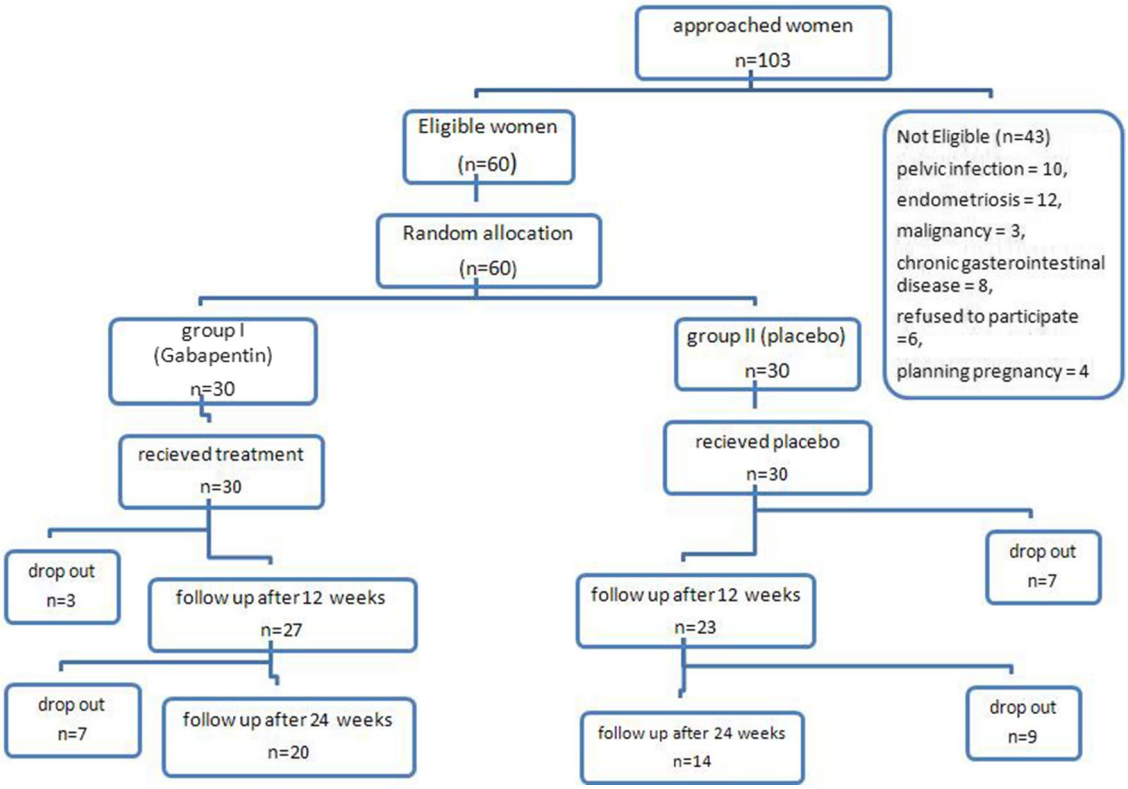

Fig. 1 Flow chart of the study

Participants received treatment with the maximum tolerated dose for a maximum of 24 weeks. We asked participants to maintain their best-tolerated dose until the end of week 24. Patients were followed up and assessed during the 24 weeks time in gynecology outpatient clinic at week 12, and 24 after initiation of treatment. Assessment of pain score has been performed using 10 cm Visual Analogue scale (VAS) with 0 denoting no pain and 10 denoting the worst ever pain. The investigator who followed up the patients and assessed the outcome was kept blind from patients' allocation. In addition, we measured overall satisfaction using Gabapentin and using 5-point Likert scale questionnaire at week 24 (1 = Very unsatisfied, 2 = unsatisfied, 3 = indifferent, 4 = satisfied, 5 = very unsatisfied).

The Primary outcome was improvement in the pain score of CPP, defined as a 30% reduction in the pain score assessed by the 10-cm VAS compared to baseline score. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations required a 30% reduction in pain score to define moderate clinically important difference in the management of chronic pain [16]. Secondary outcomes included: drug-related adverse effects, compliance with treatment (regular attendance at follow-up visits) and overall satisfaction (measured using a 5-point Likert's scale system).

Sample size calculation

Sample size was calculated setting the power $(1-)$ at 80% and the type-1 error () at 0.05. Data from a previous study [6] showed that Gabapentin administration was associated with significant reduction of the mean VAS for pain after 6 months (7.7 ± 1.5 vs. 1.6 ± 0.9, respectively, $p < 0.001$). The effect size calculated from this study was so large that any sample size can find a significant effect if there were any. Therefore, according to the proposal of Cohen proposed standardized effect size was assumed to be ≥ 0.8 (as the effect size is expected to be large). Calculation according to these values produces a minimal sample size of 25 in each group. Assuming a dropout rate of 20%, a total sample size of 60 women is needed to be randomized into two groups.

Statistical methods

Statistical analysis was to be performed using IBM© SPSS© Statistics version 20 (IBM© Corp., Armonk, NY, USA). Intention-to-treat analysis was adopted. Data were presented as number and percentage (for categorical variables); range, mean and standard deviation (for numeric parametric variables); or range, median and interquartile range (for numeric

non-parametric variables). Difference between two groups was analysed using chi-squared test and risk ratio and its 95% CI (for categorical variables); independent student's *t* test and mean difference with its 95% CI (for numeric parametric variables); or Mann–Whitney's *U* test (for numeric non-parametric variables). Significance level is set at 0.05.

Results

During the period of the study, 103 women were assessed for study eligibility, and 43 women were excluded being not fulfilling selection criteria (Fig. 1). Of the remaining 60 women, 30 were randomized to Gabapentin and 30 were randomized to placebo and were included in the final analysis. At 12 weeks of treatment three patients in the Gabapentin group, and seven patients in placebo group had dropped out. By 24 weeks, further seven patients in Gabapentin group, and nine patients in placebo group had dropped out (Fig. 1). All women enrolled in the study had chronic pelvic pain with a median duration of 16.5 months [interquartile range (IQR) 12–21]. The demographic characteristics of women included in each group are shown in Table 1.

The median value of maximum daily dose of Gabapentin was 2100 mg and the median value of time to reach the maximum dose was 5 weeks compared to 1800 mg and 4 weeks, respectively, in control group (Fig. 2). This difference was statistically insignificant.

The pain score in Gabapentin group was comparable to placebo at baseline. As shown in Table 2 pain score was significantly reduced in Gabapentin group compared to placebo at week 12 (mean = 5.12 ± 0.67 versus 5.9 ± 0.92, *p* value = 0.002) and at week 24 (mean = 3.72 ± 0.69 versus 5.5 ± 1.13, *p* value < 0.001). We found a significant reduction of pain at 24 weeks compared to pretreatment in Gabapentin group, a result that is not detected in placebo group (Table 2, Fig. 3).

At week 24, there was significantly higher proportion of patients reporting 30% or more reduction in pain scores: 19 out of 20 patients (95%) in Gabapentin group compared to 5 out of 14 patients (35.7%) in placebo group. The relative risk for pain after gabapentin treatment was 0.5 with 95% confidence interval = 0.34 to 0.75 and number needed to treat = 3 ($p = 0.007$).

Gabapentin adverse effects included somnolence, mood changes, poor concentration, and ataxia. Although it was slightly higher with Gabapentin, the incidence was comparable between both groups (Table 3). We found significantly higher incidence of dizziness with Gabapentin compared to placebo: 26.7% (8 patients) versus 3.3% (1 patient), respectively. The relative risk for dizziness was 8 with 95% CI 1.07–60.1, and number needed to harm (NNH) = 4.

The dropout rate was 33.3% (10 patients) in Gabapentin group compared to 53.3% (16 patients) in placebo group. Those women were contacted by phone and were asked about reason for discontinuing medication; 6 out of 10 women in Gabapentin group reported that this was due to development of intolerable adverse effect (dizziness) while all women in placebo group admitted it was due to no improvement with treatment.

The rate of overall satisfaction at 24-week visit was comparable in both groups with 75% (15 patients) in Gabapentin group reporting either satisfied or very satisfied compared to 57.1% (8 patients) in placebo group.

Table 1 Socio-demographic characteristics of both groups

	Gabapentin group ($n = 30$)	Placebo group ($n = 30$)
Age (years): Mean ± SD	32.7 ± 4.91	30.27 ± 5.32
Parity: Median (IQR)	3 (2–4)	3 (1–4)
BMI (kg/m^2): Mean ± SD	28.37 ± 4.67	28.35 ± 4.88
Duration of chronic pelvic pain (months)	15 (11–21)	18 (14–22)
Education level: no (%)		
Illiterate	1 (3.3%)	1 (3.3%)
Primary education	8 (26.7%)	9 (30%)
Secondary education	20 (66.7%)	18 (60%)
University degree	1 (3.3%)	2 (6.7%)
Previous pelvic surgery: no (%)		
None	25 (83.3%)	28 (93.3%)
Appendectomy	4 (13.3%)	2 (6.7%)
Ovarian/tubal surgery	1 (3.3%)	0 (0%)

BMI body mass index, *IQR* interquartile range, *SD* standard deviation

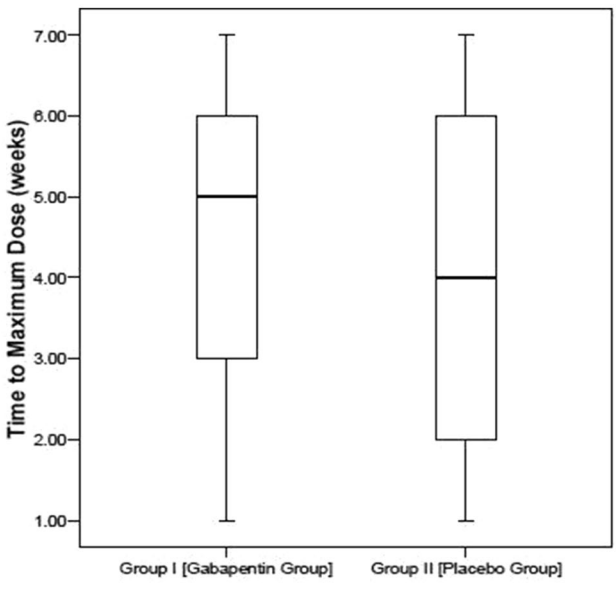

Fig. 2 Box-and-Whisker plot chart showingdifference between groups regarding time to reach maxdose

Table 2 Difference between Groups regarding pain scores

10-cm VAS for chronic pelvic pain	Gabapentin group	Placebo group	*P*
Initial ($n=30, 30$)	5.94 ± 0.73	6.09 ± 0.54	0.347*
Week 12 ($n=27, 23$)	5.12 ± 0.67	5.9 ± 0.92	0.002*
Week 24 ($n=20, 14$)	3.72 ± 0.69	5.5 ± 1.13	< 0.001*
Difference after 12 weeks	$< 0.001^{T}$	0.359^{T}	
Difference after 24 weeks	$< 0.001^{T}$	0.111^{T}	

VAS visual analogue scale, data presented as mean ± standard deviation, analysis done using:
*Student's *T*-Test, [T]Paired sample *T* Test

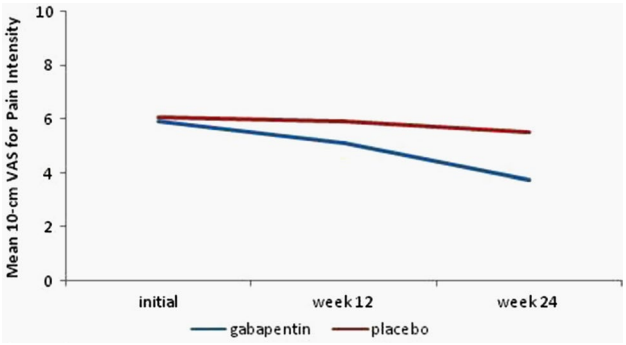

Fig. 3 Difference between Groups regarding 10 cm VAS for pain intensity

Discussion

Peripheral and central nervous systems are both involved in developing neuropathic pain [17, 18]. Central sensitization may result from interaction between ectopic discharge of peripheral nerves, *N*-methyl-D-aspartate receptor activation and disturbed spinal excitation/inhibition balance leading to chronic pain status [19]. Centrally acting agents may be used if no adequate pain control is achieved with first line therapies. Gabapentin is now gaining some popularity in managing CPP based on its ability to neutralize pain in certain chronic non pelvic pain.

In the current study, Gabapentin treatment effectively reduced pain score at 6 months after initiation of therapy, an observation that we could not detect in placebo group. In agreement with our results, an RCT [6] compared Gabapentin, Amitriptyline and both drugs in combination and reported a significant reduction in pain scores at 6, 12 and 24 months after treatment. This effect was observed with Gabapentin alone or in combination with Amitriptyline and was not reported with Amitriptyline alone.

In another pilot RCT, it was reported that Gabapentin significantly reduced chronic pelvic pain assessed by Brief Pain Inventory questionnaire (difference 1.72 points, 95% CI 0.07–3.36, *p* value = 0.04), although this finding is not supported by a significant reduction in VAS scores [9]. That study was a small pilot study which highlighted the need for larger study and the authors did not provide an in depth analysis or explanation for this finding.

In women with CPP related to endometriosis and pelvic adhesions and not responding to medical and surgical therapies, a study with multimodal approach reported Gabapentinoids effectively relieved pain resistant to first-line treatments either alone or combined with surgical interventions [20].

Gabapentin has also been shown to be effective in chronic pain management in certain neuropathic conditions. The National Institute for Health and Care Excellence (NICE), UK guideline on pharmacological management of neuropathic pain in adults recommends Gabapentin as one of the first-line management options [11]. A Cochrane review reported good evidence for Gabapentin effectiveness in post-herpetic neuralgia and peripheral diabetic neuropathy, but limited evidence for other types [21]. Other conditions with reported effectiveness included cancer pain, multiple sclerosis and vulvodinya [22]. However, this did not apply to pain related to genitourinary tract in one study [23]. In a

Table 3 Incidence of adverse effects

	Gabapentin group	Placebo group	RR (95% CI)	*p*	NNH
Dizziness	8 (26.7%)	1 (3.3%)	8.0 (1.07–60.1)	0.030	4
Somnolence	3 (10%)	1 (3.3%)	3.0 (0.33–27.2)	0.605	15
Mood changes	1 (3.3%)	0 (0%)	NE	0.999	30
Poor concentration	3 (10%)	1 (3.3%)	3.0 (0.33–27.2)	0.605	15
Ataxia	1 (3.3%)	0 (0%)	NE	0.999	30

Data presented as number (%), Analysis using Chi-Squared Test
CI confidence interval, *NE* not estimable, *NNH* number needed to harm, *RR* relative risk

retrospective study, Gabapentin significantly reduced pain in men with CPP and was more effective than pregabalin [8].

We found that dizziness was the only significant adverse effect reported among women who received Gabapentin (26.7%, NNH = 4). Other adverse effects included somnolence, mood changes, poor concentrations and ataxia and were not significantly different from placebo group. However, this trial with this sample size was actually underpowered to detect significant higher rates of such adverse effects, if they really exist.

Lewis et al. [9] reported comparable rates of adverse effects between groups treated with Gabapentin and placebo. They only reported two women with exacerbated pain requiring hospitalization but reported not to be related to Gabapentin. Less adverse effects were also reported with Gabapentin when compared to Amitriptyline [6].

In the current trial, the rates of drop-out/poor compliance were obviously high among women who received placebo (53.3% by 6 months of onset of treatment), probably owing to treatment ineffectiveness and persistent complaint. However, one-third of women who received Gabapentin also dropped-out: a rate that is relatively high. Six of those ten women who dropped out had significant reduction in their perception of pain but discontinued Gabapentin for intolerable dizziness. Significantly higher rates of women's satisfaction with Gabapentin treatment compared to placebo (30% vs. 6.7%, respectively, $p = 0.02$, NNT = 4) reflects Gabapentin effectiveness in reducing pain.

Points of strength in the current study are random allocation design, placebo controlled and double blindness, which may eliminate confounders in such a heterogeneous condition. Also we included women with no obvious cause for the condition who did not show improvement with conventional therapy allowing the evaluation of a subgroup of women with a suggested neuropathic origin of pain.

Points of weakness include relatively small sample size, particularly for drug-related adverse effects, relatively short duration of treatment, and slightly high attrition rate by end of the 6 months. In addition, the current study did not analyse the character of pain in subgroups.

Conclusion

Chronic pelvic pain in women may be treated sufficiently, although not completely, with Gabapentin. Gabapentin may be considered an alternative treatment line for cases with chronic pelvic pain, which is not relieved by analgesics.

Author contributions AMA: study conception, developed project, interpreted data, critically revised manuscript. RA: protocol development, data interpretation, manuscript writing. EA: data analysis, manuscript writing. E-ZH: project development, revised manuscript. MJM: data collection, manuscript drafting.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration of the Principles of Ethical Medical Research [last updated in Brazil 2013].

Informed consent Informed consent was obtained from all individual participants included in the study.

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