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# Sociodemographic profile, adherence, and drug interactions in patients with chronic pain treated by the Specialized Pharmaceutical Care Component of Blumenau: cross-sectional study

## Perfil sociodemográfico, adesão e interações farmacológicas em pacientes com dor crônica atendidos pelo Componente Especializado da Assistência Farmacêutica de Blumenau: estudo transversal

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## ABSTRACT

**BACKGROUND AND OBJECTIVES:** Chronic pain (CP) is a multifactorial condition that significantly affects patients' quality of life. Classified according to its pathophysiological mechanism, CP presents a variety of therapeutic challenges, in addition to its significant economic and social impact. The aim of this study was to define the sociodemographic profile, assess drugs adherence and potential drug interactions of patients diagnosed with chronic pain who take their drugs from the Specialized Component of Pharmaceutical Assistance (CEAF - *Componente Especializado da Assistência Farmacêutica).*

**METHODS:** Two instruments were used to assess drug adherence: the Morisky-Green Test (TMG) and the Brief Medication Questionnaire (BMQ). To evaluate the agreement between them, the Kappa coefficient was applied. There was a prevalence of women, white, predominantly aged between 40 and 59, married and with incomplete primary education. The search for drug interactions identified the concomitant use of gabapentin and tramadol, resulting in a high-risk interaction.

**RESULTS:** The results of the TMG indicated 65% of patients with moderate adherence and the BMQ 60% with probable low adherence, with 95% scoring in the recall domain. The Kappa coefficient showed moderate agreement at 0.58.

**CONCLUSION:** Pharmaceutical monitoring is essential to guide the use of drugs, identifying interactions and promoting greater adherence to treatment.

**KEYWORDS:** Chronic pain, Drugs from the Specialized, Drug interactions, Drug therapy, Component of Pharmaceutical Care,Medication adherence.

## RESUMO

**JUSTIFICATIVA E OBJETIVOS:** A dor crônica (DC) é uma condição multifatorial que afeta significativamente a qualidade de vida dos pacientes. Classificada segundo seu mecanismo fisiopatológico, a DC apresenta desafios terapêuticos variados, além do seu significativo impacto econômico e social. O objetivo deste estudo foi definir o perfil sociodemográfico, avaliar a adesão farmacológica e as interações farmacológicas potenciais de pacientes diagnosticados com DC que retiram seu fármaco no Componente Especializado da Assistência Farmacêutica (CEAF).

**MÉTODOS:** Foram aplicados dois instrumentos de avaliação da adesão ao tratamento: o teste de *Morisky-Green* (TMG) e o *Brief Medication Questionnaire* (BMQ). Para verificar a concordância entre eles, utilizou-se o coeficiente Kappa. Houve prevalência de mulheres, cor branca, faixa etária predominante entre 40 e 59 anos, casados e ensino fundamental incompleto. A busca por interações farmacológicas identificou o uso concomitante de gabapentina e tramadol resultando em interação de risco elevado.

**RESULTADOS:** Os resultados do TMG indicaram 65% dos pacientes com moderada adesão e o BMQ 60% de provável baixa adesão, sendo que 95% pontuaram no domínio recordação. O coeficiente Kappa apresentou concordância moderada de 0,58.

**CONCLUSÃO:** O acompanhamento farmacêutico tornasse fundamental para orientar o uso dos fármacos, identificando interações e promovendo maior adesão ao tratamento.

**DESCRITORES:** Adesão à medicação, Dor crônica, Interações farmacológicas, Medicamentos do Componente Especializado da Assistência Farmacêutica, Tratamento farmacológico.

## HIGHLIGHTS

- The main profile of patients with chronic pain treated by Specialized Pharmaceutical Care Component consisted of women, white, aged between 40 and 59 years, with incomplete primary schooling
- A "major" drug interaction risk was identified between tramadol and gabapentin, highlighting the need for continuous pharmaceutical monitoring to ensure treatment safety
- The joint application of the Brief Medication Questionnaire and Morisky-Green test revealed memory difficulties as the main barrier to medication adherence, pointing to the need for management strategies that address cognitive impairment

## INTRODUCTION

The current definition of pain by the International Association for the Study of Pain (IASP) is "[…] an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage"[1]. Regarding temporal subclassification, it can be acute or chronic. Chronic pain (CP) persists for more than three months beyond the usual time of healing for an injury, or is associated with chronic disease processes that cause continuous or recurrent pain[2]. CP can be classified according to its pathophysiological mechanism into three types: a) predominantly nociceptive pain, b) predominantly neuropathic pain, and c) mixed pain[3].

A multicenter study conducted in 1998 by the World Health Organization (WHO) showed a prevalence of CP in 22% of the world population; however, Brazilian data collected in Rio de Janeiro show a prevalence of 31%. In Brazil, other studies have mapped the prevalence of CP in some urban regions such as São Paulo with 29%, Florianópolis with 26%, and Salvador with 40%[4]. Each year, one in 10 adults is diagnosed with CP and, due to its magnitude, complexity, and high socioeconomic impact, it is considered by many authors to be a major public health problem. CP is responsible for the main causes of absenteeism at work, sick leave, early retirement, labor compensation, and low productivity[5].

According to Mendes[6], the operational structure of health care networks is composed of five components: the communication center, primary health care; secondary and tertiary points of care; support systems; logistic systems; and the health care network governance system. In this context, the Specialized Component of Pharmaceutical Assistance (CEAF) stands out as an essential element in the pursuit of guaranteeing comprehensive health care. Inserted into the secondary level of health care, the CEAF is defined as

> […] an access strategy for pharmaceuticals within the scope of the Unified Health System (SUS), characterized by the pursuit of guaranteeing the comprehensiveness of pharmacological treatment, at the outpatient level, whose lines of care are defined in Clinical Protocols and Therapeutic Guidelines (PCDT), published by the Ministry of Health.

The pharmaceuticals made available by the CEAF are included in the National List of Essential Medicines[7].

According to Joint Ordinance SAES/SAPS/SECTICS No. 1, of August 22, 2024, which approves the Clinical Protocol and Therapeutic Guidelines for Chronic Pain, the treatment of nociceptive and mixed pain follows WHO recommendations, including analgesics, anti-inflammatories, adjuvant drugs, and opioids (weak and strong). For neuropathic pain, tricyclic antidepressants and antiepileptics are indicated, with opioids reserved only for patients with pain refractory to other treatments[8]. The State List of Medicines for CEAF/SC comprises four drugs with varied presentations. The drugs listed in this list are the following: codeine 30 mg (per tablet unit), codeine 3 mg/mL as an oral solution (per bottle containing 120 mL), gabapentin 300 mg (per capsule), gabapentin 400 mg (per capsule), methadone 5 mg (per tablet unit), methadone 10 mg (per tablet unit), morphine 10 mg (per tablet unit), morphine 30 mg (per tablet unit), morphine 30 mg (in controlled-release capsules), morphine 60 mg (in controlled-release capsules), in addition to morphine 10 mg/mL as an oral solution (per bottle containing 60 mL)[9]. In this context, the present study aimed to outline the sociodemographic profile, and evaluate the adherence and pharmacological interactions of CP patients attended by the CEAF of Blumenau.

## METHODS

### Study design

This is a cross-sectional, quantitative, descriptive study conducted in the city of Blumenau (SC), involving patients who obtain their pharmacological treatment through the Specialized Pharmaceutical Assistance Component (CEAF). The interviews were conducted from May to June 2024.

### Participants

Patients included in the study comprised of previously diagnosed individuals with CP and who had access to pharmacological treatment in accordance with Joint Ordinance SAES/SAPS/SECTICS No. 1, of August 22, 2024, which approves the Clinical Protocol and Therapeutic Guidelines (PCDT) for the disease in question[8].

Inclusion Criteria: Home address in Blumenau, have a diagnosis of CP and withdraw their pharmaceuticals at the CEAF. Exclusion Criteria: Patients with physical or mental disorders that prevented the completion of the questionnaire. Patients who refused to sign the Free and Informed Consent Term (FICT).

### Variables

Sociodemographic variables were considered: age, gender, marital status, skin color, and education level.

### Assessment tools and databases

Data collection occurred using the Automated Municipal System and through interviews with patients. To evaluate adherence to pharmacological treatment and identify possible adverse effects and pharmacological interactions, the following tools were used:

Brief Medication Questionnaire (BMQ): developed by Svarstad et al.[10] and validated for the Brazilian population[11]. The classification followed the criteria:

- Adherent (no positive responses);
- Probably adherent (one positive response);
- Probably low adherence (two positive responses);
- Low adherence (three positive responses).

Morisky-Green Test (MGT): consisting of four qualitative questions, also validated for Brazil[11]. The classification was defined as: adherent (no positive responses); moderate adherence (one or two positive responses); low adherence (three or more positive responses).

Drug Interaction Checker: tool used to analyze possible drug interactions between gabapentin (medication common to all participants) and the analgesics dipyrone, paracetamol, and tramadol.

### Bias

The study showed some limitations related to selection bias and small sample size. The sample included only patients who obtain their drugs from CEAF in Blumenau and are eligible for the PCDT for CP, totaling 22 participants (20 in the adherence analysis), which prevents the generalization of results to the entire population of patients with CP. Thus, the findings reflect more of an exploratory and qualitative analysis of the profile of the service's patients than quantitative inferences about the general population.

### Sample size

The initial sample included 22 patients diagnosed with CP undergoing treatment with gabapentin through the CEAF of Blumenau. Two patients were hospitalized during the data collection period and did not answer the adherence questionnaires, resulting in 20 participants being evaluated for these instruments. The sociodemographic variables were described considering all 22 patients.

### Statistical analysis

Data analysis was performed using descriptive statistics, using Microsoft Excel® software (version 16.0.14026.20246). The Kappa coefficient, a measure of association used to assess the degree of agreement between the BMQ and TMG, was applied using the VassarStats[12] online platform. Kappa values were interpreted according to the Landis and Koch classification[13]: <0.00, no agreement; 0.00-0.20, slight agreement; 0.21-0.40, fair agreement; 0.41-0.60, moderate agreement; 0.61-0.79, good agreement; 0.80-0.99, excellent agreement. no agreement; 0.00-0.20, slight agreement; 0.21-0.40, fair agreement; 0.41-0.60, moderate agreement; 0.61-0.80, substantial agreement; 0.81-1.00, almost perfect agreement.

### Ethical aspects

This study was approved by the Research Ethics Committee of the Regional University of Blumenau (CAAE: 5370), under opinion No. 7,108,094.

## RESULTS

The research initially included 32 patients who had interviews scheduled from May to June, but 10 patients did not attend, resulting in 22 consultations being performed. An analysis of the profile of the 22 patients seen identified a greater prevalence of the female sex, white race, with the predominant age group being 40 to 59 years, married, and with incomplete primary education (36.3%).

**Table 1.** Pharmacological interactions with gabapentin.

| Drugs | Level of interaction |
|---|---|
| Dipyrone | No interaction |
| Paracetamol | No interaction |
| Tramadol | Major |

**Table 2.** Classification of adherence to gabapentin use.

| Variables | n(%) |
|---|---|
| **Adherence categories *Morisky-Green test*** | |
| Adherent (no positive response) | 6 (30.0%) |
| Moderate adherence (one or two positive responses) | 13 (65.0.%) |
| Low adherence (three or more positive responses) | 1 (5.0%) |
| **Adherence categories *Brief Medication Questionnaire*** | |
| Adherent | 0 (0.0) |
| Likely adherent | 3 (15.0) |
| Likely low adherence | 12 (60.0) |
| Low adherence | 5 (25.0) |
| **Regimen Domain** | |
| ≥1 points | 15 (75.0) |
| 0 point | 5 (25.0) |
| **Beliefes Domain** | |
| ≥1 points | 8 (40.0) |
| 0 point | 12 (60.0) |
| **Recall Domain** | |
| ≥1 points | 19 (95.0) |
| 0 point | 1 (5.0) |

The application of the questionnaires involved two losses among the 22 patients, as two were hospitalized. Given that all patients were withdrawing the drug gabapentin, an analysis of pharmacological interactions was carried out according to Table 1, focusing on this drug and other analgesics used by the patients. No risks were found with the concomitant use of gabapentin with non-steroidal anti-inflammatory drugs (NSAIDs) (dipyrone and paracetamol). The use of tramadol, a weak opioid, combined with gabapentin revealed an interaction classified by the Drugs.com[1] website as major[14].

The results obtained from the TMG pointed to six patients (30.0%) classified as adherent, 13 (65.0%) as moderately adherent, and one (5.0%) with low adherence. In comparison, according to the results of the BMQ from the 20 participants, none were classified as adherent, three (15.0%) were classified as probably adherent, 12 (60.0%) had probable low adherence, and five (25.0%) presented low adherence.

As presented in Table 2, the analysis of the BMQ test domains showed that 15 patients obtained a score equal to or greater than 1 (probable low adherence) in the regimen domain, eight in the beliefs domain, and 19 in the recall domain.

To assess the agreement between the pharmacological adherence questionnaires (BMQ and Morisky-Green), Cohen's Kappa coefficient was calculated, which measures agreement

[1] Pharmacological interactions verified on the website Drugs.com[14]

**Table 3.** Accordance between the Brief Medication and Morisky-Green questionnaires.

| Compared tools | Kappa | Standard error | CI 95% |
|---|---|---|---|
| BMQ × TMG | 0.5833 | 0.2268 | 0-0.8327 |

beyond chance. The adherence categories were separated into two groups: "adherent" and "non-adherent" (combining low/moderate adherence). The results, including a measure of precision, are presented in Table 3.

The observed Kappa was 0.5833, indicating moderate agreement between the tools. The 95% confidence interval (0-0.8327) suggests caution in interpretation, since, due to the small sample size, the observed agreement may have occurred partly by chance[13].

## DISCUSSION

Pharmacological adherence is essential to maximize treatment efficacy, especially in patients with CP, who face several challenges in the continuous management of pain. The following section discusses the sociodemographic profile, identified pharmacological interactions, and results related to adherence assessment.

The prevalence of CP mainly in female patients has already been described in studies in the literature. A systematic review that sought to identify the prevalence of CP in Brazil, with 35 articles included, observed a higher prevalence in females, with an average of 71.49% affected among the eligible studies[2]. Another study conducted in Brazil with employees of the State University of Londrina revealed a CP prevalence of 61.4% higher in women than in men. In comparison with other countries, the pattern remains. An Internet-based cross-sectional study was answered by a sample of 27,035 adult individuals in the United States (US), and the results showed that among patients with CP, the highest prevalence was among women[15]. Another study[16] analyzed the prevalence of CP in a randomly selected sample of the Australian adult population, where 17,543 interviews were conducted with a response rate of 70.8%. The results pointed to a strong association between CP and female gender. It was not possible to perform an association test in the present study due to the small number of participants.

The findings showed concomitant use of tramadol and gabapentin in most patients. As pointed out by Drugs.com[2], the concomitant use of opioids with gabapentinoids may increase the risk of opioid overdose and severe adverse effects, such as deep sedation, respiratory depression, syncope, and death due to potentially additive depressive effects on the central nervous system[14]. An observational and descriptive cross-sectional study conducted at the Municipal Central Pharmacy in Pindamonhangaba-SP quantified the main drug interactions among service users, among which tramadol in combination with gabapentin stood out. Opioids are commonly used in the treatment of CP and are often associated with adjuvant drugs such as gabapentin. These patients should be monitored to avoid and minimize the risk of adverse effects[17]. Within this scenario, the importance of pharmaceutical care in monitoring the pharmacological treatment of these patients stands out, reducing the associated risk. According to Hepler and Strand[18], the objective of pharmaceutical care is to provide continuous care, focusing on the prevention and resolution of drug-related problems, promoting increased safety and efficacy of drug therapy.

The BMQ is widely used in the assessment of drug adherence, providing a robust analysis through its domains. The present study observed higher scores in the recall domain in 95% of patients. In addition, 75% of patients scored in the regimen domain, which assesses adherence to the prescribed regimen, focusing on the patient's ability to follow instructions for taking drugs, including dose and frequency. These findings can be explained by memory impairment in patients with CP, which has been widely discussed in the literature.

A previous study[19] demonstrated, through an animal model study, that CP compromises spatial memory formation and reduces neurogenesis in the dentate gyrus of the hippocampus, suggesting a correlation between CP and memory deficits. A literature review concluded that patients with CP often report having a "poor memory," corroborating several studies. Although mild, these effects on memory have a significant impact by amplifying emotional distress, anxiety, and depression, as well as factors associated with drug adherence and quality of life of patients.

These aspects raise concerns about cognitive dysfunction associated with pain or the use of analgesic drugs included in treatment, highlighting the importance of including memory assessment in the approach and guidance of patients[20]. Moreover, a systematic review with meta-analysis reinforced the cognitive deficit in people diagnosed with CP, including impaired attention and memory loss, classifying CP as a risk factor associated with cognitive decline with relevant impacts on the patient's quality of life[21].

Regarding the beliefs domain, 40% of patients scored in this aspect, which seeks to assess the patient's perception of the need for and effectiveness of treatment. At this point, it is worth noting that these patients often report discomfort with the adverse effects of drugs, leading to interruption and compromise of pharmacological treatment. Opioids are widely used in the treatment of CP. Their analgesic action occurs through interaction with opioid receptors. Although this is a common approach in patients diagnosed with CP, their use is challenging due to the risks associated with adverse reactions to the drug itself and indiscriminate use by patients, which can even lead to death[22]. The use of gabapentin was reported by all patients, and some of the adverse effects found in the literature include sedation, ataxia (usually mild and transient), and lower limb edema[23].

The TMG comprises four questions, which aim to assess patient behavior regarding daily medication use. In its original study dated 1986, the questionnaire showed sensitivity of 43.6% and specificity of 81%[24]. The results obtained showed that 65% of patients had moderate adherence, i.e., they had one or two positive responses. This

[2] Pharmacological interactions verified on the website Drugs.com[14]

data suggests that a significant portion face difficulties following the pharmacological regimen, affecting pain control and quality of life.

In order to address these difficulties, a meta-analysis that reviewed 569 studies reported an average non-adherence rate of 20.6% among various chronic conditions. In patients with CP, more than 60% used drugs, However, adherence remains a challenge, with 29.9% taking less medication than prescribed and 13.7% taking more than necessary[25].

The Kappa coefficient showed moderate agreement (0.58) between the questionnaires, demonstrating that although they are tools that address different aspects, with the BMQ being more comprehensive and the TMG simpler and more direct, their combined use is relevant to provide a broader and more complete view of adherence. The BMQ is a more robust and comprehensive assessment tool that explores different areas of treatment, capturing not only practical adherence behaviors but also cognitive, emotional, and social barriers. The TMG, on the other hand, offers a simpler and more direct approach, focused on medication-taking behavior. The questions focus on forgetfulness, carelessness, or interruption of treatment due to a feeling of improvement or perception of worsening, making this test particularly effective in identifying patients with simple behavioral problems[24].

Together, these tools enable the identification of behavioral aspects, discomfort with drug use, and social, emotional, and cognitive factors. This analysis is especially crucial in patients with CP to understand the barriers to pharmacological treatment[19,23]. A study of hypertensive patients treated from January to September 2010 was conducted[11] at a primary care unit in Porto Alegre, RS. The TMG and BMQ tests were used to assess drug adherence, and internal consistency, temporal stability, and performance were analyzed in relation to three gold standards. The results revealed that the BMQ questionnaire performed better than the TMG, with greater sensitivity and specificity[11].

A cross-sectional and analytical study conducted at an outpatient clinic in the city of São Paulo, SP, with 117 elderly individuals between March and November 2019, analyzed the association between adherence and barriers to pharmacological therapy with social support in the elderly. The methodology used was based on the BMQ to identify barriers to treatment adherence from the patient's perspective, while the TMG was used as a more simplified approach to assess treatment adherence patterns[26].

Claudino and Lacerda[27] sought to evaluate adherence to immunosuppressive treatment in patients treated at a renal therapy unit, using the BMQ to explore patients' perceptions of treatment efficacy and adverse effects, as well as to investigate drugs administration. In combination, they applied TMG to assess habits related to regular drug use[27]. Other similar studies also used both instruments to analyze adherence to treatment for various diseases[28,29].

## CONCLUSION

The study revealed the predominant profile of CP patients and identified memory difficulties as a significant barrier to adherence to the treatment drugs. A multimodal approach to treatment and access to drugs via the CEAF proved essential. The detection of a relevant drug interaction between tramadol and gabapentin reinforces the need for pharmaceutical monitoring, thus ensuring the safety and efficacy of treatment.

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**AUTHORS' CONTRIBUTIONS**

**Helena Luiza Kirsten Sasse:** Statistical Analysis, Data Collection, Conceptualization, Resource Management, Project Management, Research, Methodology, Writing - Preparation of the Original, Writing - Review and Editing, Visualization
**Luana Gabriele Nilson:** Writing - Review and Editing, Visualization
**Mônica Cristina Nunes:** Data Collection, Project Management, Writing - Review and Editing, Supervision, Visualization