Pain induction by chemotherapy medication docetaxel in women with breast cancer

Indução da dor pelo quimioterápico docetaxel em mulheres com câncer de mama

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Abstract

Objective: To describe the frequency, characteristics, location, pain intensity in breast cancer patients using the chemotherapy medication Docetaxel.

Methods: Longitudinal study involving 17 women with breast cancer under treatment using Docetaxel. The patients' pain was assessed during three chemotherapy cycles, using the tools McGill Pain Questionnaire (Br-MPQ) and the Brief Pain Inventory (BPI). Spearman's correlation and the Mann-Whitney test were used.

Results: The mean pain score increased in all variables of the BPI. When comparing the total coefficients on the Pain Assessment Index, 0.20; 0.33 and 0.24 were found in the first, second and third assessment, showing a correlation between the pain intensity and the interference in all daily activities on the BPI for the second assessment.

Conclusion: The occurrence of pain increased, compromising the participating women's activities of daily living.

Resumo

Objetivo: Descrever a frequência, características, localização, intensidade da dor em pacientes com câncer de mama em uso do quimioterápico *Docetaxel*.

Métodos: Estudo longitudinal realizado com 17 mulheres com câncer de mama em tratamento com *Docetaxel*. As pacientes foram avaliadas durante três ciclos da quimioterapia quanto à dor, utilizando-se os instrumentos Questionário *McGill* de Dor (Br-MPQ) e *Brief Pain Inventory* (BPI). Utilizou-se a correlação de *Spearman* e o teste de *Mann-Whitney*.

Resultados: Houve aumento na média da dor em todas as variáveis do BPI. Quando comparados os valores do *Pain Rating Index* (PRI) total foram verificados respectivamente 0,20; 0,33 e 0,24 na primeira, segunda e terceira avaliações, sendo encontrada correlação entre a intensidade da dor e a interferência em todas as atividades do cotidiano no BPI na segunda avaliação.

Conclusão: Houve aumento na ocorrência da dor, comprometendo as atividades diárias de vida das mulheres participantes.

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Introduction

According to the International Association for the Study of Pain (IASP), pain "is an unpleasant sensory and emotional experience associated with actual or potential tissue damage".[1] Pain can be acute or chronic, visceral or somatic, neuropathic or psychogenic, the latter being common in oncology patients.[2]

One widely used chemotherapy medication to treat breast cancer is Docetaxel. Docetaxel is one of the drugs in the pharmacological group called "taxanes". These derive from a natural substance found in the bark of the yew, *Taxus baccata*, a tree that produces both toxic (taxanes) and medicinal substances (taxol). Taxanes (paclitaxel and docetaxel) are antimitotic medications that act on the microtubules of tubulin by stabilizing them. The rupture of the cellular equilibrium changes the cell structure and its functions, resulting in apoptosis. Paclitaxel and Docetaxel are used to treat cancer with a significant therapeutic response, particularly in women with lymph node problems.[3] Among the adverse reactions experienced by patients on Docetaxel, peripheral neuropathy was classified in the drug monograph as a common adverse reaction that affects about 30% of the patients.[4] This adverse reaction affects the nervous system, classifying the medication as neurotoxic.[5]

The characteristic symptoms of neuropathic pain are tingling, numbing and pain in the hands and feet; fine motor problems; difficulty to walk; loss of deep tendon reflexes, transitory muscle pain and arthralgias, especially in joints and limbs.[5]

Patients on taxanes, such as Docetaxel, may experience muscular pain or arthralgia. These reactions have been called "acute pain syndrome associated with taxanes, probably resulting from peripheral nerve injury and sensitization of nociceptors". On average, these start one or two days after the infusion of the chemotherapeutic drug and, on average, they last four to five days.[6]

Pain is a symptom that is hard to assess, due to its subjective, complex and multidimensional nature.[7] The tools used to assess the pain can be divided between multidimensional and one-dimensional.[8]

The origin of pain is multifactorial, causing changes in the biopsychosocial and spiritual aspects, requiring an interdisciplinary team to diagnose and treat patients with painful syndromes that are hard to control.[8]

This study is justified as the pain can significantly interfere in the accomplishment of different activities of daily living, and consequently in the quality of life of patients being treated. Through the measuring and assessing of the pain, individualized nursing and interdisciplinary care can be planned, focused on the control and/or elimination of the pain as an adverse reaction of Docetaxel use, and on the improvement of quality of life, as patients being treated with taxanes need individual pharmacokinetic adjustments, according to the clinical response, comorbidities, medication interactions and adverse reactions experienced.

The objective of the study was to describe the frequency, characteristics, location and intensity of the pain, as well as to analyze the repercussion of the pain intensity on the activities of daily living of the patients studied.

Methods

A descriptive and longitudinal study with a quantitative approach was undertaken. The sample consisted of the total population of women attended during the data collection period, i.e. 17 women with breast cancer being treated with Docetaxel. The inclusion criteria were women over 18 years of age, undergoing neoadjuvant treatment exclusively with Docetaxel, and with intact comprehension and communication skills. Women with impaired cognitive skills were excluded from the study.

One of the researchers, an undergraduate nursing student, collected the data at the chemotherapy outpatient clinic of the Oncology sector of a public teaching hospital in the city of Uberlândia, State of Minas Gerais, in the Southeast of Brazil, between December 2012 and September 2013. To collect the data, a previously selected tool was applied when the patients were awaiting multidisciplinary team care and during the chemotherapy sessions.

The medical history was used as a secondary source of information.

The women who accepted to participate in the study signed the Free and Informed Consent Form and answered three data collection tools to assess and characterize the pain: the identification and characterization form, the Brazilian version of the McGill Pain Questionnaire (Br-MPQ)[9] and the Brief Pain Inventory (BPI - Brief Pain Inventory.[10]

The Br-MPQ consists of a set of 68 descriptors, divided in four categories: sensory, affective, subjective assessment and mixed. For the sake of this study, the Pain Assessment Index and the Number of Words Chosen were verified. The Number of Words Chosen ranges from zero to a maximum of 20. The Pain Assessment Index is based on each word's gradual score. In the 20 classes, the pain descriptors are ranked in an increasing order of intensity.

The BPI is a multidimensional pain measure that included 15 items, subdivided in two parts: the first assesses the pain intensity between zero (absence of pain) and 10 (unbearable pain); the second assesses the interference of the pain in daily activities, such as general activity, mood, ability to walk, work, relationship with other people, sleep and appreciate life, which is also assessed on a numerical scale from zero (did not interfere) to 10 (completely interfered).

All study participants received four cycles of doxorubicin + cyclophosphamide, followed by four cycles of Docetaxel, administered at 21-day intervals. During the treatment using doxorubicin + cyclophosphamide, the pain was not assessed, as the study was only focused on pain related to Docetaxel. The assessments took place at three distinct times, longitudinally distributed as follows: first assessment, before the start of the chemotherapy infusion using Docetaxel; second and third assessment, after the second and third cycles, respectively. As the interval between the chemotherapy cycles for breast cancer ranges between 21 and 28 days, the development and conclusion of the treatment was not delayed for any of the patients. Although no research data were collected in the final cycle using Docetaxel, it was observed during the nursing care and clinical pharmacy monitoring that the final cycle of Docetaxel was suspended in one of the patients due to tumor progression, while the dose was reduced in two patients due to severe toxicity. During the data collection, none of the participants was lost.

The collected data were typed in Microsoft Excel 2007 worksheets, with double data entry for the sake of greater reliability. The software used was Statistical Package for the Social Sciences (SPSS), version 22.0 for Windows. Spearman's correlation was used to analyze the association between the pain intensity in the variable "Worst pain in the last 21 days" and "Interference of pain in activities of daily living", and the correlation between the Pain Assessment Index and the Number of Words Chosen. The Mann-Whitney test was applied to verify the correlation between the Pain Assessment Index and the use of medications. Significance was set with a p-value of 0.05.

The Pain Assessment Index (sensory, affective, evaluative, mixed and total) was found according to the score attributed to each of the categories, corresponding to the index between the sum of the intensity obtained in each of the categories and the total possible score in each category.[11]

The pain variables at the three assessment times according to the BPI are displayed as means, standard deviations, minima and maxima in women undergoing chemotherapy with the medication Docetaxel.

The study was registered on *Plataforma Brasil* under *Certificado de Apresentação para Apreciação Ética* (CAAE): 06890012.9.0000.5152.

Results

The sociodemographic, economic and clinical characteristics are displayed in table 1.

During the first assessment, the average score for the variable worst pain in the past 21 days was 4.94 (minimum and maximum score: zero to 10; standard deviation: 3.41); the average score for the variable weak pain in the past 21 days was 1.88 (minimum and maximum: zero to

5; standard deviation: 1.65) and the mean pain score was 3.76 (minimum and maximum: zero to 8; standard deviation: 2.68). In the second assessment, the average score for worst pain in the past 21 days was 8.12 (minimum and maximum: 5 to 10; standard deviation: 1.53); the average for weak pain in the past 21 days was 3.65 (minimum and maximum: zero to 7; standard deviation: 1.96); and the mean pain score was 5.12 (minimum and maximum: 2 to 8; standard deviation: 1.53). In the third assessment, the average score for worst pain in the past 21 days was 6.82 (minimum and maximum: 2 to 10; standard deviation: 2.24); the average for weak pain in the past 21 days was 2.82 (minimum and maximum: zero to 8; standard deviation: 1.74); and the mean pain score was 3.59 (minimum and maximum: 1 to 7; standard deviation: 1.73).

Table 1. Distribution of study participants according to sociodemographic, economic and clinical characteristics

Characteristics	n(%)
Age range	
30-40	3(17.65)
41-50	3(17.65)
51-60	9(52.94)
≥61	2(11.76)
Marital status	
Single	1(5.88)
Married	12(70.50)
Separated/divorced	2(11.76)
Widowed	2(11.76)
Skin color	
White	7(41.17)
Black	4(23.52)
Mulatto	6(35.29)
Education, years	
<9	10(58.88)
≥9	7(41.17)
Income, minimum wage*	
≤1	5(29.41)
>1-2	4(23.52)
>2-3	4(23.52)
>3-5	2(11.76)
>5	2(11.76)
Clinical staging	
IIA	4(23.52)
IIB	6(35.29)
IIIA	5(29.41)
IIIB	2(11.76)
Use of analgesic medication	
First assessment	5(29.41)
Second assessment	8(47)
Third assessment	14(82.32)

*Minimum wage in force at the time of the research: R$678.00

The relation between pain intensity in the variable worst pain in the past 21 days and interferences in activities of daily living is presented in table 2.

Table 3 presents the Pain Assessment Index and the Number of Words Chosen in averages for the first, second and third assessments. It should be highlighted that Pain Assessment Indices closer to one corresponded to higher pain levels.

To explore the relation between the Pain Assessment Index and the Number of Words Chosen, the Spearman correlation test was applied, but no correlation was found in any of the assessments.

The Mann-Whitney test was applied to verify the relation between the patients' medication use and the Pain Assessment Index, but no correlation was found between these variables. In the first assessment, 70.58% of the patients did not use any pain control medication. In the second assessment, 17.65% used non-steroidal anti-inflammatory medication, 17.64% weak opioids and 11.76% strong opioids. In the third assessment, only three patients did not use analgesics.

Emotional problem and physical effort were appointed as the most interfering factors. When asked about the cause of the increased pain, we found: movement, emotional problem and no perceived

Table 2. Relation between pain intensity in the variable worst pain in the last 21 days

Variables	Worst pain in the last 21 days					
	First assessment		Second assessment		Third assessment	
Activities of Daily Living	Coefficient	p-value*	Coefficient	p-value*	Coefficient	p-value*
General assessment	0.770	0.000*	0.589	0.013*	0.704	0.002*
Mood	0.598	0.011*	0.488	0.047*	0.825	0.000*
Ability to walk	0.677	0.003*	0.833	0.000*	0.607	0.010*
Work	0.659	0.004*	0.698	0.002*	0.499	0.041*
Relationship with other people	0.309	0.121	0.567	0.0188*	0.606	0.010*
Sleep	0.393	0.119	0.617	0.008*	0.679	0.003*
Appreciate life	0.702	0.002*	0.572	0.016*	0.370	0.144

*p-value <0.05

Table 3. Pain Rating Index (PRI) and Number of Words Chosen (NWC)

Variables	First assessment		Second assessment		Third assessment	
	PRI	NWC	PRI	NWC	PRI	NWC
Sensory	0.19	3.41	0.34	5.65	0.24	4.53
Affective	0.20	1.82	0.35	3.12	0.28	2.53
Subjective assessment	0.30	0.65	0.51	1	0.38	1
Mixed	0.10	0.76	0.12	1.24	0.07	0.82
Total	0.20	6.63	0.33	10.98	0.24	8.86

PRI-*Pain Rating Index*; NWC-*Number of Words Chosen*

cause; hence, several causes can contribute to the increase or appearance of the pain. As for the strategies to decrease the pain, resting/relaxation was appointed as the main strategy for pain relief, corresponding to 41% in the first assessment, 29.4% in the second assessment and 52.9% in the third assessment.

What the pain location is concerned, the following locations and respective percentages were appointed: in the first assessment, the patients appointed the lower limbs (52.9%), followed by the upper limbs (29.4%) and head (29.4%) as the body areas with the most intense pain. In the second assessment, 100% of the patients referred that the lower limbs were the body area with the most intense pain, followed by the upper limbs (64.6%) and back (64.6%). In the third assessment, the lower limbs (82.32%), upper limbs (41.16%) and back (35.28%) were appointed as the body areas with intense pain.

Discussion

Most (52%) participants were between 51 and 60 years of age. These data were expected, as studies confirm that breast cancer is relatively rare before the age of 35 years.[12] After the age of 50 years, the incidence rates display a progressive and fast increase, age being the main risk factor for the appearance of breast cancer.[13] The white skin color was observed in 58% of the women, very similar to the findings in another study.[14] In 29% of the participants, the family income was one minimum wage, and education inferior to nine years prevailed. These results demonstrate that the patients attended at this public health institution have low educational and socioeconomic levels, representing an important bottleneck to understand the orientations proposed. The nurses should make sure to make the language easy to understanding, facilitating communication and aiming for its understanding.[15]

The increase in the mean pain score was found in all BPI variables when comparing the first with the second and third assessments. In the univariate analysis, a correlation was found between pain intensity and interference in all daily activities in the BPI during the second assessment ($p<0.05$). The greater interference in these aspects consequently entails a worse quality of life. The variables the pain affects in the three assessments were general activity, mood, ability to walk, work and appreciate life. In the BPI aspects "relationship with other people" and "sleep", statistical significance was only found in the second and third assessments. A study of post-treatment pain in women with breast cancer found similar results. The pain most strongly affected the following aspects: mood, normal work and sleep. In a systematic review to assess the incidence of the acute pain syndrome induced by taxanes in breast cancer patients, the authors concluded that pain was a clinically significant adverse event that interfered in the activities of daily living and reduced the participating patients' quality of life.[16] Untreated pain causes anxiety and depressive symptoms, also impairing the cognitive functions and entailing great losses in daily and social activities and sleep. The pain can act as a limiting factor for the accomplishment of activities of daily living and leisure, besides causing changes in the body image and reducing the frequency and pleasure of sexual activities; the pain can result in significant changes in the quality of life when compared to women without pain.[17] Therefore, the team members' educational work is extremely important, highlighting the nursing professionals.[18]

By means of the Br-MPQ, the different pain dimensions (sensory, affective, evaluative and mixed) could be assessed. When the Pain Assessment Indices were compared between the first and the second and third assessments, increased coefficients, and therefore increasing pain intensities were found. Also, the pain intensity increased after the start of the treatment using Docetaxel. The subjective assessment category stood out because the highest increase in the pain index was found. This analyzes, estimates and summarizes the strength and importance of the global subjective discomfort the presence of the pain causes in perceptual as well as reactive terms. It represents pain as a form of self-knowledge and self-assessment.[9]

Higher pain intensity and, consequently, higher Pain Assessment Indices were found in the second assessment. In the third assessment, the mean Pain Assessment Indices were lower than in the second assessment. This result may be justified by the fact that no prophylaxis exists to prevent this neuropathic pain in patients who have started treatment with Docetaxel. After the first Docetaxel cycle, according to the patients' complaints, analgesics need to be prescribed. Thus, during the third assessment, the patients would already be on correct analgesic and, consequently, experiencing lower pain levels. The growing use of analgesic medications during the second and third assessments can prove this fact. In view of the individual and subjective characteristics of pain and the pain threshold, no standard analgesia can be used, so that each patient's individual complaints need to be verified to adopt the correct and effective conduct.

An increase was found in the mean NWC in all categories when comparing the first and the second assessment. In the data analysis, no statistical correlation was found between the Pain Assessment Index and the Number of Words Chosen. This result can be explained by the fact that the Number of Words Chosen is an additional index, which can hamper the analysis of statistical significance. The Number of Words Chosen does not necessarily drop when partial relief is obtained. The patients frequently choose a less intense word from a subclass or category instead of not using the entire subclass or category. That naturally results in a lower Pain Assessment Index, but does not lead to a change in the Number of Words Chosen.[9]

Simultaneously with the increase in the pain intensity, the use of analgesics increased significantly, with the progressive use of stronger medications, starting with non-steroidal anti-inflammatory agents until reaching strong opioids. Nevertheless, no correlation was observed between the Pain Assessment Index and the use of analgesics. In the first assessment, 70.58% of the patients did not use any pain control medication. In the second, there was an enhanced drop in the number of patients who did not take any medication.

During the three assessment times for the data collection, it was verified that the patients appointed the lower limbs as the body area with the highest pain intensity, corresponding to 52.9% in the first assessment, increasing to 100% in the second assessment and 82.32% in the third assessment. Next, the upper limbs were appointed as the body area with the greatest pain intensity. In this respect, the number of patients increased considerably in the second assessment when compared to the first. The back was the third most appointed region with the highest pain intensity. The results found in this study are in line with the literature, where the patients tend to report greater pain in the lower limbs when compared to the upper limbs.[19] Normally, the pain starts between 24 and 48 h after the Docetaxel infusion, with an average length of three to five days. The neuropathy can continue for months and even years though.[16]

This study's contributions related to the most detailed knowledge on Docetaxel-induced neuropathic pain, an important adverse reaction that affects women with breast cancer. This kind of studies supports the establishment of nursing interventions and can help with the management and reduction of neuropathic pain and its sequelae in the short, medium and long terms, contributing to improve the patients' quality of life through qualified nursing care. There is no proven medication currently to prevent or treat chemotherapy-induced peripheral neuropathy. Therefore, a gap is also verified in the literature.

Nevertheless, evidence has already been published on the use of effective non-pharmacological strategies.[20]

As a multiprofessional team member, the nurse can systematically assess the pain, being the professional who spends most time and has most contact during patient care. As the responsible for continuing care, nurses can outline nursing interventions for the sake of appropriate pain control, providing comfort, safety and wellbeing. In a multidisciplinary activity, nursing can also manage the patients' medication therapy to adjust doses in due time; monitor the infusion time of the chemotherapy medication, control the volume infused and monitor the cumulative dose. These fundamental measures will promote the success of the treatment and reduce the toxic levels of Docetaxel. Thermotherapy, massages, walks, therapeutic touch, attitude change, distraction, relaxation techniques, reiki, acupuncture, acupressure and music therapy should be part of the nursing and/or pharmaceutical prescription; these are considered alternatives that knowingly improve the patients' quality of life.[21]

Neuropathy is an important factor that leads to dose reduction, treatment delay or interruption, being one of the first-choice management options to reduce this adverse reaction. In this study, none of the patients needed to interrupt the treatment or delay the chemotherapy cycle, although two patients had the Docetaxel dose reduced due to severe toxicity. In view of the importance of Docetaxel in the adjuvant and neoadjuvant therapies for breast cancer treatment, as well as its ole in the prevention of relapse, Docetaxel-induce peripheral neuropathy lacks further studies to explore appropriate management forms, without causing losses for the treatment but being able to maintain the patients' quality of life.[22,23]

The limits of this study were mainly related to the small sample size, as the population is very specific, despite including the entire population of women who complied with the inclusion criteria in the study context, in view of the established data collection period. Thus, new studies are needed with larger samples. It should also be kept in mind that the tools used, BPI and Br-MPQ, were not fully suitable for the assessment, characterization and measuring of neuropathic pain. Further studies are extremely important to assess neuropathic pain using suitable tools, such as the NCI (National Cancer Institute) scale, the CTCEI 4.0[24] and the TNS-r,[25] considering that, as mentioned earlier, no effective pharmacological interventions exist, although the interventions influence the symptoms. These study results can contribute to nursing care, as they establish nursing interventions that can result in better conditions to cope with the treatment and its adverse reactions, granting a better quality of life to the patients.

Conclusion

The mean pain score increased in all variables of the Brief Pain Inventory and the pain assessment index when the first assessment was compared with the second and third. In addition, a statistically significant association was found between pain and the variables general activity, mood, ability to walk, work and appreciate life when the first assessment was compared with the second and third. As a result of the growing pain, analgesic medication was increasingly used.

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Collaborations

Neris RR, Anjos ACY and Magnabosco P contributed to the conception of the project, the analysis and interpretation of the data, the writing of the article, relevant critical review of the intellectual content and final approval of the manuscript for publication. Amaral PA and Ribeiro MA cooperated with the critical review of the intellectual content and the approval of the final version for publication.

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