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Non-Invasive Study of Intracranial Pressure in Pre- and Post-Chemotherapy Patients for the Treatment of Breast Neoplasia

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ABSTRACT

Introduction: Breast cancer is the most common type among women and brings to them significant organic changes. A new intracranial pressure monitorization method consists of an external system of sensors that detects micrometric deformations on the cranial bones and transmits, in real-time, electrical signals that are visualized on a monitor. **Objective:** To identify changes in intracranial pressure due to chemotherapy connections through non-invasive methodology. **Methods:** The present study was conducted at Hospital Santa Casa de Misericordia in the city of Ponta Grossa, PR, Brazil in 2017. The variables P2/P1 ratio (ICP morphological evaluation), laboratory parameters, comorbidities, and clinical aspects of the volunteers were evaluated. The vascular toxicity of chemotherapy often causes endothelial dysfunction, resulting in a loss of vasodilation effects and suppresses anti-inflammatory and vascular repair functions. **Results:** The values of the P2/P1 ratio before and after chemotherapy were also compared between groups. A statistically significant difference was observed in the pre-chemotherapy P2/P1 values compared to the post-chemotherapy values. **Conclusion:** Variations in ICP may occur in cancer patients. Further studies are necessary to evaluate if this change may contribute to the chemotherapy side effects occurrence.

Keywords: drug therapy; intracranial pressure; vascular capacitance; breast neoplasms.

INTRODUCTION

Cancer occurs due to changes in the cell division process that promote rapid and abnormal growth when compared to the normal physiological proliferation process[1]. Breast cancer is the most common type among women, and it is considered rare before 35 years, but after that age, the rates tend to increase progressively[2].

Breast cancer is the most prevalent cancer in women in all major regions of Brazil[3]. The mortality rate is increasing and represents the leading form of cancer death in the Brazilian female population, with 17,572 deaths in 2018[4]. Some main predisposing factors are family history, age, early menstruation, late menopause, obesity, no history of pregnancy, and replacement hormones[5].

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Adverse reactions caused by chemotherapy are commonly reported by patients, symptoms such as dizziness, craving, and vomiting, for example[6,7]. The same symptoms can appear in patients who show changes in intracranial pressure[8]. In this context, could the monitoring of these patient's intracranial pressure (ICP) be a tool that would contribute to clinical management and increase their quality of life?

Currently, the applied method to monitor intracranial pressure demands to drill the skull and introduce the sensors surgically. However, a non-invasive method for measuring ICP has been developed. This method consists of an external system of chips that transmits, in real-time, electrical signals that are visualized on a monitor[9]. To measure ICP, the sensor detects micrometric deformations on the cranial bones. The received signals are then amplified, digitized, and sent to a monitor, where it is possible to visualize the morphology of the ICP[10,11] wave (Figure 1).

Through the non-invasive method, the ICP waveform is related to brain compliance. The wave morphology in question has three peaks, P1, P2, and P3, which are associated with the wave of systolic blood pressure transferred by the choroid plexus, P2 is associated with the reflection of the systolic wave in the parenchymal tissue and P3 are related to the closure of the aortic valve[12].

A compliant brain is expected to see three peaks in decreasing fashion. The wave morphology, according to Nucciet al.[13], can be divided into five classes, ranging from normal to ground, as the peaks behave differently from what is expected. From the amplitude of the wave and the height of the P1 and P2 peaks, a value is calculated, where the results below or equal to 0.90 are understood to be normal. When P2 is greater than or equal to P1 this value becomes greater than 0.91, in these cases it is possible to obtain essential information related to the change in the ICP[14]. Other works carried out divide these values only into two classes, normal and altered. P2/P1 values considered normal are <1.0, while altered values are >1.0[15].

In our study, we considered normal <0.9, a zone of alteration between 0.91 and 1.09, while abnormal >1.10. This division was adopted considering the pathological morphological alteration, which generates these values that are not normal but are not yet altered[13,15].

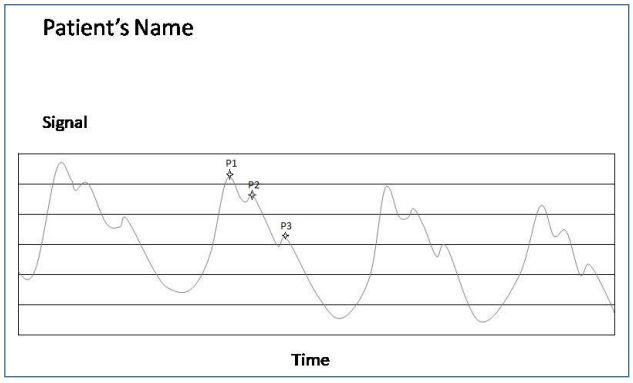

Figure 1: Representative illustration of ICP wave morphology. Adapted from Guia de Uso Brain4Care, 2019.

Cancer usually requires a combination of different treatment modalities. Tumors are susceptible to surgery, radiotherapy, and chemotherapy, as well as combinations of different anticancer drugs. Most of these conventional drugs have been designed to target deoxyribonucleic acid (DNA) at the time of cell division. However, since tumor cells are not the only proliferating cells in the body, problems also develop. The cells lining the digestive tract, bone marrow cells, and epidermal cells are all highly proliferative. Thus, cancer patients undergoing chemotherapy suffer from side effects that limit treatment[16].So preventive measures are necessary to avoid or soften collateral effects such as dizziness, craving, and vomiting[17,18].

Considering that several factors can change ICP in cancer patients, such as the presence of brain metastases and the chemotherapy treatment itself, a non-invasive method for monitoring ICP in this population would be useful. A non-invasive method for monitoring ICP would help the study of the pathophysiology of the disease and it could provide an auxiliary tool for complications during chemotherapy[17,18].

Establish a clinical and laboratory profile of the patients, correlating them with the ICP data. Check if there is a difference in cerebral compliance between the 1st, pre-chemotherapy, and 2nd, (post-chemotherapy) ICP monitoring. Assess whether there are correlations between information from ICP monitoring with clinical data (blood pressure (BP), blood count, and creatinine). Define whether there is a relationship between the chemotherapy of volunteers and brain compliance. Compare the data obtained from the group of cancer patients compared to those in the control group.

This study aimed to evaluate how the morphology of the ICP wave of patients with breast cancer is presented in the face of the chemotherapy treatment submitted.

METHODS

The present study was conducted at *Hospital Santa Casa de Misericordia* in the city of Ponta Grossa, PR, Brazil. The selected patients were informed about the research and participated in it voluntarily after signing the Free and Informed Consent Form. This study was conducted after authorization by the Research Ethics Committee of the State University of Ponta Grossa, number 2.072.638 (CAAE:49403421.2.0000.0105).

Selection of subjects

This is a case-control study, the sample size was defined according to the number of volunteers available at the oncology center who underwent periodic chemotherapy.

The volunteer patients were called the test group (breast cancer patients undergoing chemotherapy), and the control group was formed from the employees who worked during the period when monitoring occurred (volunteers without cancer and, therefore, not undergoing chemotherapy). The number of selected for each equivalent group, considering their clinical characteristics and certain variables, such as age, weight, and comorbidities.

Thus, for the test group, the inclusion criterion was chemotherapy performed for breast cancer at the oncology outpatient clinic of the institution where the research was conducted. For the control group, the primary inclusion criterion was the absence of diagnosed neoplasms or chronic diseases. The control group also only included hospital employees and volunteers who did not have any ties, but those characteristics like the participants in the control group, such as age and weight. Exclusion criteria for both groups included receiving chemotherapy treatments at home; having a substance use disorder or other mental illness, being pregnant, and being underage.

Collection of clinical and personal data

The noninvasive ICP monitor was provided by the company Brain4Care®(https://brain4.care/en/). The pre-chemotherapy measurement was performed before the participants started their chemotherapy infusions. To measure their ICP, the participants were asked to remain immobile for five minutes. At the end of the chemotherapy session, the same ICP monitoring procedure was performed again for another five minutes. The ICP morphology in this research was differentiated on three levels. Normal ICP was considered when P2/P1 ratio ≤ 0.90. Threshold ICP was considered when the P2/P1 ratio was between 0.91 and 1.09. Abnormal ICP was presented when the P2/P1 ratio was equal to or larger than 1.10. Thus, the analysis of the ICP morphology allowed us to assess the subjects' brain compliance.

Other clinical data, such as age, weight, height, comorbidities, and temperature, were obtained through the hospital's computerized health records and through personal interviews conducted on the days that the patients underwent chemotherapy treatments.

For the control group, volunteers were accepted to perform ICP monitoring and collect data from pre-existing clinical examinations. At the meeting with these women, where ICP monitoring was conducted, under the same conditions as the study group, that is, all seated trying not to move. Clinical data and the results of existing laboratory tests were also collected.

Laboratory exams

The laboratory results were obtained by consulting the electronic medical records of the participants, and parameters such as complete blood count and creatinine were considered.

Statistical analysis

Statistical analysis was performed to compare the ICP of the test group, pre- and post-chemotherapy, with the control group. For these analyses, the Kolmogorov-Smirnov test was applied to assess the normality of the data. As most of the clinical and laboratory characteristics did not present a normal distribution, we present the median and interquartile range for continuous variables, and for categorical variables, we present the absolute (n) and relative (%) frequency. The possible differences between the groups were analyzed using the Mann-Whitney test. The P2/P1 ratios showed normal distribution and are presented as mean and standard deviation. The paired P2/P1 ratios obtained before and after chemotherapy were analyzed by the student'st-test for paired samples. However, the results of the control group the test group before and after chemotherapy were analyzed by the student'st-test for independent samples. In all analyses, the level of significance was pre-fixed at $p<0.05$. The data were evaluated using the statistical program SPSS 20.0®.

RESULTS

The clinical characteristics of this study's test and control groups are shown in Table 1. Among the most prevalent comorbidities, systemic arterial hypertension stands out, agreeing with the consulted literature followed by diabetes mellitus, hypertriglyceridemia, osteoporosis, and aortic aneurysm[5].

To identify whether there was ICP change (P2 greater than P1 and P3) and to determine if any of those changes are pathological, the wave morphology of the patients was analyzed through the P2/P1ratio, following the previously described interpretation. Before chemotherapy, all subjects from the test group exhibited normal ICP during monitoring. After chemotherapy, all subjects from the test group presented P2/P1 ratios larger than the pre-chemotherapy ones. Some of the subjects' ICPs were classified as pathological due to chemotherapy P2/P1 ratio values larger than 1.1. Some complications were also observed, such as dizziness, headache, and retching. However, it was not possible to relate these symptoms to ICP changes. Other test group subjects presented slightly changed ICP due to ratio values after chemotherapy between 0.90 and 1.09. Although some test volunteers' ICP were normal after chemotherapy, they presented higher values than the ones observed before chemotherapy.

Five (18%) subjects from the test group exhibited abnormality in their ICP, seven (26%) exhibited results at the threshold of abnormality, and fifteen (56%) did not show a change in the morphology of their ICP wave (although P2/P1 ratio was greater than the ones before chemotherapy). The subjects from the control group presented normal ICP (P2/P1 ratio did not exceed 0.9 for all subjects in this group).

The BP of the patients was measured only before the chemotherapy session, so it was not possible to compare it with the BP after the session.

Considering the post-chemotherapy assessment, the values of the P2/P1 ratio were compared as follows (Figure 1): i) pre-chemotherapy test group X post-chemotherapy test group; ii) control group X pre-chemotherapy test group; and iii) control group X post-chemotherapy test group.

The values of the P2/P1 ratio before and after chemotherapy were also compared between groups. The control group presented a mean P2/P1 ratio equal to 0.818 ± 0.066 and the test group presented a mean ratio equal to 0.816 ± 0.096 before chemotherapy and 1.008 ± 0.137 after chemotherapy. So, there was a statistical difference between the pre-and post-chemotherapy test group ($p<0.0001$) and between the control and post-chemotherapy group ($p<0.0001$). However, there was no statistical difference between the control group and the pre-chemotherapy test group ($p=0.944$) (Figure 2).

In the present study, the total leukocyte count was evaluated for all participants (Table 2). The blood counts demonstrated that the test group was within the normal range[13].

DISCUSSION

ICP reveals the relationship between the contents of the cranial box, the brain, cerebrospinal fluid, and blood. The volume of these components tends to remain constant since a change in the volume of one of these items can lead to a change in ICP[18].ICP waveforms consist of three peaks named P1, P2, and P3. Normal ICP presents the following relative amplitudes: P1>P2>P3. ICP changes are evidenced with P2 amplitude higher than the other two peaks[16].The ratio between P2 and P1 peak amplitudes may be used to evaluate patients' ICP, and a ratio equal to or below 0.90 is considered normal[16,19].

The vascular toxicity of chemotherapy often causes endothelial dysfunction, resulting in a loss of vasodilation effects and suppressed anti-inflammatory and vascular repair functions[20]. In this study, it can be seen again that chemotherapy can directly influence one of the components of ICP, the volume of circulating blood, and may indirectly alter brain complacency. The data obtained for this study is compatible with the which indicate, according to Cameron et al.[20], that vascular complications can occur as side effects of chemotherapy.

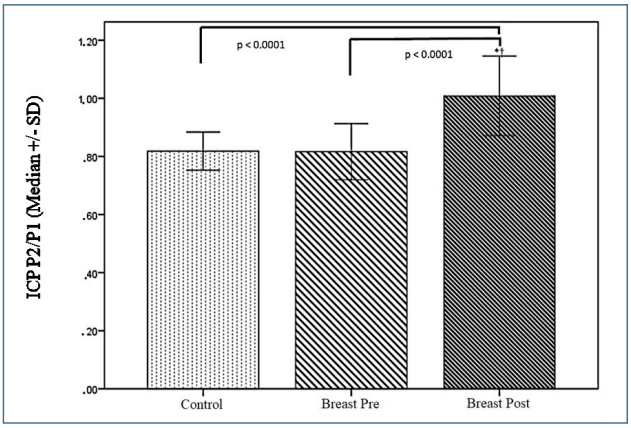

Figure 2: Bar diagram showing the mean and standard deviations of the P2 / P1 ratio for the control and test groups before and after chemotherapy. *Statistical difference about the control group ($p<0.05$). † Statistical difference between the pre- and post-chemotherapy groups ($p<0.05$).

Table 1: Characterization of the groups studied: control and breast cancer.

Clinical parameters	Control (n=22)	Breast (n=27)	Value p
Age, (Years)	43 (53 – 47)	48 (39 – 59)	0.700
Weight (Kg)	70.0 (65.5 – 76.2)	66.0 (59.0 – 71.0)	0.201
Height (m^2)	1.64 (1.59 – 1.64)	1.62 (1.53 – 1.67)	0.359
BMI (Kg/m^2)	27.02 (24.39 – 28.33)	26.95 (22.77 – 29.75)	0.962
SBP (mmHg)	120 (120 – 130)	110 (110 – 130)	0.321
DBP (mmHg)	80 (80 – 80)	70 (60 – 80)	0.023*
Comorbidities, n (%) †			
Systemic Arterial Hypertension	2 (9)	7 (26)	-
Diabetes Mellitus	1 (5)	3 (11)	-
Dyslipidemia	0 (0)	1 (4)	-
Cardiovascular Diseases	1 (5)	1 (4)	-
Absence	18 (89)	16 (59)	-

Median and interquartile range values or absolute (n) and relative frequency (%).
Mann-Whiteney Test.
* Statistical difference between the groups studied ($p<0.05$).
† Descriptive statistics only
BMI, bodymass index; SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 2: Median values and interquartile range of laboratory parameters of the studied groups: control and breast cancer

LaboratoryParameters	Control (n=22)	Breast (n=27)	Value p
Erythrocytes (Millions/μL)	4.47 (4.26 – 4.61)	4.01 (3.67 – 4.19)	< 0.001*
Hemoglobin (g/dL)	12.85 (12.25 – 13.82)	12.10 (10.80 – 12.90)	0.009*
Hematocrit (%)	37.55 (36.58 – 39.10)	35.10 (31.20 – 37.10)	0.002*
MCV (fL)	84 (81 – 86)	87 (84 – 90)	0.011*
MCH (pg)	29.50 (28.20 – 30.19)	30.30 (29.10 -31.20)	0.013*
MCHC (%)	34.84 (34.30 – 35.16)	34.65 (33.96 – 35.31)	0.507
Total leukocytes (/μL)	7.215 (5.270 – 8.962)	4.970 (3.610 – 6.590)	0.006*
Neutrophils (/μL)	4.126 (2.819 – 4.978)	3.198 (2.022 – 4.628)	0.064
Lymphocytes (/μL)	2.306 (1.538 – 3.315)	1.165 (1.015 – 1.582)	< 0.001*
Platelets (/μL)	233,000 (203,000 – 275,000)	247,000 (197,000 – 304,000)	0.651
Neutrophil / Lymphocyte	1.55 (1.34 – 2.39)	2.31 (1.68 – 2.79)	0.028*
Creatinine (g/dL)	0.81 (0.72 – 0.87)	0.79 (0.63 – 0.87)	0.296

Mann-Whiteney Test.
* Statistical difference between the groups studied (p<0.05).
MCV, mean corpuscular volume; MCH, mean corpuscular hemoglobin; MCHC, mean corpuscular hemoglobin concentration.

We emphasize that due to the modernity of the method, it was not possible to compare the results obtained with the literature, however, studies that adopt the traditional technique relate the presence of intracranial hypertension in cancer patients[7].

The noninvasive method was previously compared to the traditional invasive one allowing us to consider both similar. Saline was infused into the spinal channel of rats to produce ICP changes and the simultaneous acquisition of both methods was performed[10]. The non-invasive method contradicts the Monroe-Kellie doctrine, which dictated that the skull has no movement and, to measure the ICP, it would be necessary to pierce it and insert catheters through a surgical procedure[19].

The amplitude of the P1 peak, during monitoring, must be greater than the other two peaks used to assess the patients' ICP, in a P2/P1 ratio the ratio between them must be equal to or less than 0.90 to be considered ICP of normal monitoring[10,20-22].

This methodology has been studied and applied in various fields within healthcare, such as patients with end-stage renal disease, women with migraine, women with high and minimal risk of pregnancy, and patients undergoing sedation for gastrointestinal endoscopy, among others. In addition, those studies evaluate the morphology of ICP waves from the non-invasive method and compare it with invasive techniques[10,15,21-26].

The non-invasive monitoring of the ICP consists of a tension meter attached to a mechanical device that touches the scalp in the parietal region lateral to the sagittal suture. The sensor can detect small cranial deformations resulting from changes in the ICP. The method still does not produce pressure values calibrated in millimeters of mercury but provides continuous information about the ICP waveform[27].

From this, it was possible to perceive the changes in patients with breast cancer, and the main statistical differences will occur in the comparison between the measurements before and after the chemotherapy session. As well as between patients in the control group and patients with cancer after chemotherapy.

Thus, the use of non-invasive ICP monitoring for patients undergoing chemotherapy sessions may detect significant changes that could contribute to side effects related to the treatment.

According to Ulsenheimer et al.[28], the most crucial factor in the blood count for cancer monitoring is the white series, as the pathology affects the body's immune response. Although the total leukocyte count demonstrated that the test group was within the normal range, there was a statistically significant difference from the control group, demonstrating that the subjects who did not undergo chemotherapy had a higher total leukocyte count, thus corroborating the researched literature[28].

In Table 1, test and control groups were equivalents considering Age (years), Weight (Kg), Height (m), BMI (Kg/m^2), and systolic blood pressure (mmHg). Although diastolic blood pressure (mmHg) was significantly different, both groups were considered normal to this parameter. The comorbidities occurrence in both groups could be a crucial factor in limiting this study's interpretation and must be clarified in new research to understand how they could interfere with ICP measurements.

Another parameter considered before chemotherapy sessions is platelets. People who experience a drop in platelet count during chemotherapy may need a dose reduction or a longer interval between chemotherapy cycles. This is at risk of bleeding if a surgical approach is required, in which case the surgery is usually delayed until the platelet count is at a normal level[29].

Considering that several chemotherapeutic agents are eliminated by the kidneys and can interfere with kidney function, the creatinine dosage of patients undergoing treatment is also performed, to make sure that their metabolism will not be overloaded[30].The parameters mentioned above were evaluated in the individuals participating in this research and considered adequate, again agreeing with what appears in the literature[29].The other laboratory parameters evaluated, such as the red series, did not show significant changes in the results.

Conclusion

Variations in ICP occur in cancer patients. It is believed that such changes result from chemotherapy treatment that interferes in many ways, directly and indirectly, with the components that create ICP. However, it was not possible to identify exactly why chemotherapy causes changes in ICP. We were also unable to relate the complications, such as dizziness, nausea, and vomiting, to the changes since they can occur for several reasons. Thus, we believe it is necessary to serial monitor ICP, through Brain4Care® technology, in patients undergoing chemotherapy treatment to identify when they start exhibiting changes in ICP and seek to correlate those changes with the complications reported. The clinical parameters were equivalent in both groups. The laboratory parameters showed some differences that agree with the literature, but do not influence the results of the ICP.

It was observed that the cerebral complacency of the volunteers in the control group and the cancer patients before the chemotherapy session. As well as the change in intracranial compliance in patients in the test group after the chemotherapy session, complementary studies are being developed to determine when the changes start.

Thus, based on the results obtained in this study, we believe that the Brain4Care® method may be useful in the future for oncology centers and clinics, contributing to the clinical evaluation of these patients and collaborating in the management of eventual complications. To reach the clinical applicability further studies are suggested to be conducted to confirm the changes submitted.

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